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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re EFFEXOR XR ANTITRUST LITIGATION This Document Relates To: Direct Purchaser Class Actions	Lead case no. 3:11-cv-05479 (Direct)

DIRECT PURCHASER CLASS PLAINTIFFS' SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND JURY DEMAND

TABLE OF CONTENTS

I. INTRODUCTION 1

II. JURISDICTION AND VENUE 6

III. THE PARTIES....6

IV. REGULATORY AND ECONOMIC BACKGROUND 9

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs....9

1. The Hatch-Waxman Amendments....10

2. Paragraph IV Certifications 11

3. Effects of AB-rated generic competition. 13

4. The first and later AB-rated generics are priced below the brand. 14

5. Authorized generics are a significant form of price competition. 16

V. FACTS 18

A. Wyeth Obtains the Original Compound Patent for Effexor....18

B. Wyeth Develops Extended Release Venlafaxine Products....19

1. Wyeth Develops Spheroid Encapsulated Extended Release Venlafaxine. 19

2. Alza's Development of an Osmotic Shell Extended Release Venlafaxine. 22

3. Clinical Studies for Wyeth's Extended Release Formulation....23

4. Wyeth's Early 1990s Efforts to Get Further Patent Protection for Venlafaxine. 23

5. Alza's Early 1990s Efforts to Secure Patent Protection. 25

B. Wyeth Fraudulently Obtains Method-of-Use Claims in Three Effexor XR Patents 27

1. The Application History of the Invalid and Unenforceable '171, '958, and '120 Patents....28

1. The Prior Rejection Invalidity and Fraud: Wyeth Failed to Disclose a Previous Examiner's Rejection of Independent Method-of-Use Claims...31

2. The Nausea Fraud: Wyeth Fraudulently Claimed Clinical Data Showed a Reduction in Nausea and Vomiting 53

3. The Unexpected Discovery Invalidity and Fraud: Wyeth Fraudulently Claimed Extended Release Venlafaxine was "Unexpected." 63

C. Wyeth Engaged in Sham Litigation against Fifteen Generic Manufacturers 73

1. Teva....76

2. Impax 86

3. Anchen 87

4. Lupin 88

5. Osmotica 89

6. Sandoz....90

7. Mylan 90

8. Biovail....92

9. Apotex....92

10. Torrent....93

11. Cadila 93

12. Aurobindo 94

13. Orgenus and Orchid 95

14. Intellipharmaceutics....95

15. Wockhardt....96

16. Dr. Reddy's 96

17. Nostrum....97

D. Earlier Allegations and Evidence of the Invalidity and Unenforceability of Wyeth's '171, '120, and '958 Patents....97

VI. MONOPOLY POWER AND MARKET DEFINITION....99

VII. MARKET EFFECTS 101

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE....104

IX. CLASS ACTION ALLEGATIONS 105

X. CLAIMS FOR RELIEF 108

XI. DEMAND FOR JUDGMENT....114

XII. JURY DEMAND 115

I. INTRODUCTION

1. Direct Purchaser Class Plaintiffs (whose full names and addresses are given below in paragraphs 17 through 20) bring this antitrust class action against Defendants Wyeth and Teva (described in paragraphs 21 through 30) for damages resulting from the delayed market entry of generic versions of Wyeth's branded antidepressant Effexor XR, an encapsulated extended release version of the compound venlafaxine hydrochloride.

2. Although Wyeth's marketing exclusivity for the original venlafaxine compound patent lapsed on June 13, 2008, the first generic equivalent of Effexor XR was foreclosed for two more years, until June 2010. Other generics were foreclosed until June 2011. The reason: Wyeth engaged in an anticompetitive scheme to prevent and delay the approval and marketing of generic versions of Effexor XR. Wyeth's scheme included (i) fraudulently procuring three patents for extended release formulations of venlafaxine hydrochloride, (ii) wrongfully listing those patents in the FDA Orange Book as covering Effexor XR, (iii) engaging in serial sham litigation to block and delay multiple generic companies, (iv) entering into a horizontal market-allocation and price-fixing agreement with generic manufacturer Teva, and (v) negotiating settlements with subsequent generic applicants to preserve and protect its monopoly and market-division agreement with first-filer Teva.

3. The early phase of Wyeth's blocking strategy had to overcome two challenges. First, by the 1990's pharmaceutical formulators knew so much about how to slow down the release of chemicals like venlafaxine that there were few novel approaches left. Second, the kind of narrow formulation patent that might properly emerge in this setting would be a low bar; generic competitors could and would simply design around the specific formulation. So what to do?

4. Wyeth resorted to fraud.

5. *Wyeth's Fraudulent Patent Procurement.* Through a series of fraudulent acts, Wyeth was able to obtain broad method-of-use claims in three patents that primarily addressed specific formulations of extended release venlafaxine: U.S. Patent Nos. 6,274,171 ("the '171 patent), 6,419,958 ("the '958 patent"), and 6,403,120 ("the '120 patent"). These three patents ostensibly extended Wyeth's monopoly on extended release venlafaxine hydrochloride capsules by nine years, until March 20, 2017. But Wyeth was only able to obtain these patents by misrepresenting and concealing material information to the U.S. Patent and Trademark Office (the "PTO"). Wyeth knew that under the scrutiny of patent infringement litigation there was no realistic likelihood that a court would, ultimately, enforce the '171, '958, or '120 patents against a generic manufacturer. But Wyeth needed only a patent to use as a vehicle to *bring* an infringement action. Wyeth would avoid the inevitable loss by settling the lawsuits before courts ruled on the merits.

6. Wyeth's overarching scheme included three separate frauds on the PTO:

7. *Wyeth's Nausea Fraud.* All three fraudulently obtained patents included method-of-use claims for decreasing the incidence of nausea and vomiting. Wyeth told the PTO that clinical data showed that Wyeth's extended release version of venlafaxine hydrochloride, Effexor XR, reduced the incidence of nausea and vomiting associated with instant release Effexor. Wyeth offered no other support for these claims. In truth, no such clinical data existed. The nausea method of use claims would never have issued but for Wyeth's misrepresentation to the PTO.

8. *Wyeth's Unexpected Discovery Invalidity and Fraud.* Wyeth fraudulently claimed that its purported discovery of an extended release version of Effexor was "completely unexpected," despite knowing that (i) an earlier Wyeth patent (the Upton patent) had disclosed

extended release versions of Effexor (ii) an earlier, published, patent application by a Wyeth collaborator (the '589 PCT application) had also disclosed extended release versions of Effexor, (iii) one skilled in the art would be aware of several methods for achieving extended or sustained release formulations, (iv) Wyeth had already successfully created a long-acting formulation of propranolol (Inderal LA), a similarly soluble compound with a similar peak blood concentration time, and (v) Wyeth had already successfully developed an Effexor XR formulation by substituting venlafaxine for propranolol in the Inderal LA formulation. In reality, extended release venlafaxine was expected and easily created. None of the claims of any of the three fraudulently obtained patents would have issued if Wyeth had not made the intentional and highly material misrepresentations that its supposed discovery of extended release venlafaxine was "completely unexpected," Wyeth had adequately disclosed its relevant knowledge and previous experiences to the PTO.

9. *Wyeth's Prior Rejection Invalidity and Fraud.* Wyeth used a Trojan horse to obtain method-of-use claims in a series of ostensible formulation patents for a specific encapsulated spheroid approach to extending the release of venlafaxine. Wyeth's patent applications included a few ambiguously phrased method-of-use claims. One reading of the claims limited the method-of-use claims to Wyeth's encapsulated spheroid formulations. But another interpretation would appear to protect *any* method of using extended release venlafaxine to spread the dosage over time – *regardless* of the particular formulation. Ironically, the first PTO examiner reviewed Wyeth's first application, caught onto Wyeth's sleight of hand, observed that the method-of-use claims could be interpreted broadly, and rejected Wyeth's broad method-of-use claims as unpatentable – since these methods of use would be obvious to one skilled in the art.

10. Once discovered, Wyeth agreed to amend its method-of-use claims to be tied to the particular formulations Wyeth was seeking to patent, but then abandoned that application (including formulation claims the first examiner had found patentable), opting to try again with another patent examiner. Wyeth refilled applications that included the previously rejected method-of-use claims. Wyeth then failed to disclose to later examiners (i) that the original patent examiner had found its method-of-use claims unpatentable and (ii) that Wyeth had agreed with this rejection.

11. *Wyeth's Wrongful Orange Book Listings and Serial Sham Litigation.* After obtaining the '171, '120, and '958 patents, Wyeth used them to continue its scheme to block generic versions of Effexor XR from the market. Wyeth listing all three patents in the Orange Book and promptly filing baseless patent infringement litigation against each and every generic manufacturer that tried to bring an extended release venlafaxine product to market. Wyeth alleged that generic manufacturers were infringing its '171, '120, and '958 patents – patents Wyeth knew to be invalid and/or unenforceable – in fifteen sham lawsuits. Every generic manufacturer responded by pointing out that Wyeth's patents were invalid and/or unenforceable. But each suit triggered an automatic two-and-a-half year stay of FDA approval.

12. *Wyeth and Teva's Conspiracy.* Wyeth then settled all fifteen sham lawsuits before a court determined whether the fraudulently-obtained method-of-use claims were invalid and/or unenforceable. The settlements were "win-win" for Wyeth and first generic filer Teva – they prolonged Wyeth's market exclusivity far beyond its lawful protection of mid-2008 and enabled Teva to maintain and extend its generic exclusivity rights. Wyeth paid Teva value worth over $500 million in exchange for Teva's agreement not to market its generic version of Effexor XR until June 2010. First, the payments included an agreement by Wyeth not to compete with

Teva through a promise that Wyeth would not launch an authorized generic version of Effexor XR during the 180-day exclusivity period. Without competition from Wyeth's authorized generic, Teva would realize about double the volume of generic sales at significantly higher, supra-competitive prices than Teva otherwise would receive absent Wyeth's promise. In words and effect, under the Wyeth-Teva agreement, Wyeth provided a financial inducement amounting to over $500 million dollars to Teva in exchange for Teva's agreement to delay generic entry. Second, the agreement ensured that Wyeth would challenge the efforts of other would-be generics to enter the market early, and that Wyeth would resolve any subsequent generic lawsuits before they advanced to findings of invalidity and/or non-infringement. Since such findings would otherwise trigger Teva's exclusivity rights and void the Wyeth promise not to compete with an authorized generic, Wyeth's promise thus assured Teva it would in fact receive the payments worth over $500 million dollars that Teva stood to realize from the no-authorized-generic provision.

13. If Wyeth had not fraudulently obtained the method-of-use claims, listed the fraudulently obtained patents in the Orange Book, brought sham infringement actions, and/or colluded with Teva, generic extended release venlafaxine products would have launched for sale in June of 2008. Absent its fraud and other wrongful conduct, Wyeth could not have extended its monopoly in the market for extended release venlafaxine hydrochloride capsules beyond June 2008 through the settlements of its improper patent lawsuits – since those lawsuits would not have existed absent Wyeth's fraud in obtaining and/or listing the allegedly infringed patents. Moreover, absent the Wyeth-Teva conspiracy, Wyeth would have launched an authorized generic on or about the date that Teva launched its generic, i.e., in June 2008.

14. As a result of Wyeth's fraud and other exclusionary conduct, generic versions of Effexor XR were illegally blocked from the marketplace from at least June 2008 through at least June 2010. During this period of foreclosure, U.S. retail sales of Effexor XR topped *$4.5 billion*. Direct purchasers paid significantly more for extended release venlafaxine hydrochloride capsules during this two year window (and continue to pay more for Effexor XR and its generic equivalents) than they would have in the absence of Wyeth's illegal anticompetitive acts.

II. JURISDICTION AND VENUE

15. This action arises under sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2) and section 4 of the Clayton Act (15 U.S.C. §15(a)) to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiffs and members of the Direct Purchaser Class resulting from Defendants' unlawful foreclosure of the market for extended release venlafaxine hydrochloride capsules. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), 1337(a), and 15 U.S.C. § 15.

16. Wyeth and Teva transact business within this district. Venue is appropriate within this district under section 12 of the Clayton Act (15 U.S.C. § 22) and 28 U.S.C. §1391(b) and (c).

III. THE PARTIES

17. Plaintiff Professional Drug Company, Inc. ("Professional Drug") is a corporation organized under the laws of the State of Mississippi that purchases pharmaceuticals directly from manufacturers. Professional Drug's principal place of business is 186 Bohn Street, Biloxi, Mississippi 39530. Professional Drug purchased Effexor XR directly from Defendant Wyeth during the class period. Wyeth's unlawful anticompetitive conduct injured Professional Drug.

18. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with a principal place

of business located at 50 Jet View Drive, Rochester, New York 14624. RDC purchased Effexor XR directly from Wyeth, and generic Effexor XR directly from Teva, during the class period. Wyeth's unlawful anticompetitive conduct injured RDC.

19. Plaintiff Stephen L. LaFrance Holdings, Inc. is a holding company with interests in retail and wholesale distribution. Its corporate office is located in Pine Bluff, Arkansas. Plaintiff Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors (collectively with Stephen L. LaFrance Holdings, Inc., "LaFrance") is a wholly owned subsidiary of Stephen L. LaFrance Holdings, Inc. and is its distribution company with interests in retail and wholesale drug distribution. Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors' corporate office is located in Pine Bluff, Arkansas. LaFrance is the assignee of McKesson Corporation, who purchased Effexor XR directly from Wyeth during the class period and was injured by the illegal conduct alleged herein.

20. Plaintiff Uniondale Chemists, Inc. is a retail pharmacy located in Uniondale, New York. Uniondale Chemists is the assignee of QK Healthcare, Inc., who purchased Effexor XR directly from Wyeth during the class period and was injured by the illegal conduct alleged herein.

21. Defendant Wyeth – a/k/a Wyeth LLC, f/k/a Wyeth, Inc., f/k/a American Home Products – is a corporation organized and existing under the laws of the state of Delaware. Wyeth's principal place of business is Madison, New Jersey. On information and belief, American Home Products changed its name to Wyeth, Inc., and Wyeth, Inc. later changed its name to Wyeth LLC. Wyeth is now a wholly owned subsidiary of Pfizer.

22. Defendant Wyeth Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the state of Delaware with a principal place of business in Collegeville,

Pennsylvania. Wyeth Pharmaceuticals, Inc. is a member of Wyeth Pharmaceuticals Division and is a wholly owned subsidiary of Wyeth.

23. Defendant Wyeth-Whitehall Pharmaceuticals ("Wyeth-Whitehall") is a corporation organized and existing under the laws of Puerto Rico and having a place of business at Road No. 3, KM. 142.1, Guayama, Puerto Rico 00784. Wyeth-Whitehall is in the business of pharmaceutical preparation and is a subsidiary of Wyeth.

24. Defendant Wyeth Pharmaceuticals Company ("WPC") is a corporation organized and existing under the laws of Puerto Rico and having a place of business at Road No. 3, KM. 142.1, Guayama, Puerto Rico 00784. WPC is in the business of pharmaceutical wholesale products and is a subsidiary of Wyeth.

25. Defendants Wyeth and Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall and WPC are referred to collectively as "Wyeth."

26. Throughout this complaint, the phrase "the Wyeth applicants" refers to Wyeth, the named inventors of the fraudulently-obtained patents, the prosecuting attorneys of the fraudulently-obtained patents, and agents thereof. The Wyeth applicants include, but are not limited to: inventors John C. Clark, John U. Lamer, Deborah M. Sherman, and Steven A. White as well as attorneys Ronald W. Alice, Rebecca Barrett, Egon Berg, Robert Boswell Jr., Steven R. Eck, and Arthur Seifert. The term also includes any agents of these persons from Wyeth.

27. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva USA is in the business of developing, manufacturing and marketing pharmaceutical products, primarily generic products, in the United States. Teva Pharmaceuticals USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

28. Defendant Teva Pharmaceutical Industries Ltd. is an international corporation, headquartered and having a place of business at 5 Basel St. Petach Tikva 49131, Israel, engaged in the development, manufacturing, marketing and distribution of pharmaceuticals. Through its subsidiaries, a large portion of Teva Pharmaceutical Industries Ltd.'s sales are in the United States and Teva Pharmaceutical Industries Ltd. has major manufacturing operations in the United States. Teva Pharmaceutical Industries Ltd. is the parent company of Teva Pharmaceuticals USA.

29. Defendants Teva USA and Teva Ltd. are referred to collectively as "Teva."

30. Teva and Wyeth will be referred to hereinafter collectively as "Defendants."

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a) & (b).

32. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §§ 355 (b) (1) & (c) (2).

33. The FDA relies completely on the brand manufacturer's truthfulness about a patent's validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

1. The Hatch-Waxman Amendments

34. The Hatch-Waxman Amendments enacted in 1984 simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may file an Abbreviated New Drug Application (ANDA). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is bioequivalent to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.[1]

35. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic

[1] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. § 314.54.

drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j) (8) (B).

36. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

37. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, pre-Hatch Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of all prescriptions.

2. Paragraph IV Certifications

38. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

39. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer brings a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of two and a half years, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market before the passage of thirty months or a court decision of invalidity or non-infringement.

40. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, *i.e.*, all generics (other than one marketed by the branded manufacturer) are kept off the market for at least six months.

41. The high profit margins on brand name drugs, and the predictable effects of generic entry – sales switch quickly from the brand to the generic – create powerful financial incentives for brand name manufacturers to list patents in the Orange Book – even if such patents are not eligible for listing – and sue any generic competitor that files an ANDA with Paragraph IV certifications – even if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable – in order to delay final FDA approval of an ANDA for up to 30 months.

42. By creating a statutory mechanism to enable early infringement litigation following paragraph IV certifications, the Hatch-Waxman Amendments foster patent litigation between generic and branded drug companies as a method to test the validity of outstanding pharmaceutical patents and encourage generic manufacturers to invent around branded patents. The notion is that *bona fide* litigation will result in rulings that either confirm legitimate patent protection or ferret out illegitimate use of invalid or unenforceable drug patents.

3. Effects of AB-rated generic competition.

43. Typically, AB-rated generics cost much less than their branded counterparts. Over time, as more generic equivalents enter the market for a drug and compete with each other, prices decline rapidly. Because generic products are commodities that cannot be differentiated, the primary basis for generic competition is price.

44. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often capturing 80% or more of the market within the first six months. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of brand sales and (with multiple generics on the market) prices had dropped 85%. See FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, January 2010 at *http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf*.

45. Brand manufacturers are well aware of the generics' rapid erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

4. The first and later AB-rated generics are priced below the brand.

46. Generics may be classified as (i) first filer generics, (ii) later generic filers, and (iii) authorized generics.

47. When a first generic manufacturer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the branded product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first generic has been on the market for 180 days.[2] ANDA filers that wait until all Orange Book listed patents expire before marketing their product do not get a 180-day reprieve. Congress created this 180-day window to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

48. This 180-day window is referred to as the first filer's six-month or 180-day "exclusivity." The label is partially erroneous because, while later ANDA-approved generic makers must wait six months after the first filer's market entry to get FDA approval, a brand's "authorized" generic may enter at any time; this market dynamic is described below.

49. The Supreme Court has recognized that "this 180-day period of exclusivity can prove very valuable, possibly worth several hundred million dollars"[3] to the first filer.

[2] 21 U.S.C. 355(j)(5)(B)(iv).

[3] *FTC v. Actavis*, 133 S.Ct. 2223 (2013) (citation omitted).

50. The 180-day period is even more valuable to the first filer – likely far more than twice as valuable – if the brand does not launch an authorized generic. Without the authorized generic, the first filer is left with all generic sales during the 180 day period -- and possibly beyond, if no other generic is ready, willing or able to launch a generic pursuant to an approved ANDA after 180 days.

51. Experience and economic research show that the first generic manufacturer to enter the market prices its product below the prices of its branded counterpart.[4] Every state either requires or permits that a prescription written for the branded drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule (branded plus generics).

52. During the 180-day exclusivity period, the first filer generic is the only ANDA-approved generic maker on the market. It is often the case that most of a first filer's profits are earned during the first six months of market entry.

53. If during the six-month exclusivity there is also no authorized generic on the market, then the first filer (being the *only* generic on the market) prices its product below the brand product, but not as low as if it were facing competition from other generics, including an authorized generic. Since in these circumstances the first filer's product competes only with the brand, and because the branded company rarely drops the brand price to match the first filer, the first filer does not face the kind of price competition it will when additional generic products, including an authorized generic, are available.

[4] Saha, A., H. Grabowski, H. Birnbaum, P. Greenberg and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," International Journal of the Economics of Business, n. 1, v. 13 (February 2006), pp. 15-38 ("Saha, et al. (2006)") (For 40 drugs that experienced generic entry between July 1992 and January 1998, the average price of generics was 76% of the brand price one month after generic entry).

54. Thus it is when multiple generic competitors enter the market that one sees the competitive process accelerate and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[5]

55. According to the FDA and the FTC, the greatest price reductions are experienced when there are two generics on the market. In that situation, there are two commodities that compete mostly if not entirely on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of around more than 10%, but that with two generic entrants near term retail price reduction is about 50%.

56. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. A 2009 FTC Study found that generics captured between approximately 72% and 85% of sales in the first six months.[6] In the end, total payments to brand manufacturers for the drug decline to a small fraction of the amounts paid prior to generic entry.

5. Authorized generics are a significant form of price competition.

57. The brand manufacturer has the right to sell a generic version of its own branded product, a so-called "authorized generic." An authorized generic is essentially the branded product (manufactured according to its FDA-approved New Drug Application) in different (generic) packaging.

[5] *See, e.g.*, Danzon, Patricia and Li-Wei Chao, "Does Regulation Drive Out Competition in Pharmaceutical Markets?," *The Journal of Law and Economics*, Oct. 2000; Regan, Tracy, "Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act," Working Paper, Department of Economics, University of Miami, February 14, 2004; Frank, R., "The Ongoing Regulation of Generic Drugs," *The New England Journal of Medicine*, v. 357, n. 20 (November 2007), pp. 1993-1996 ("Frank (2007)").

[6] FTC Study, Federal Trade Commission, "Authorized Generics: An Interim Report," June 2009.

58. Authorized generics are priced like other generics and compete on price with other generics. A 2006 study sponsored by the brand drug company trade group, PhRMA, for example, found that the presence of an authorized generic causes generic prices to be 16% lower than when there is no authorized generic.[7]

59. Branded manufacturers can also begin pre-selling authorized generics a few months *before* the first-filer generic launches, in order to secure multi-year purchase contracts with direct purchasers and "load the generic pipeline" at the expense of the first-filer generic.

60. One study notes that "...pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[8] A study by Berndt gives three examples of authorized generics, finding that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[9] And the FTC's 2009 study shows prices with authorized generic entry are lower during the 180-day exclusivity period.[10]

61. As a result, a competitive pharmaceutical marketplace includes authorized generic entry during the (misnamed) 180-day exclusivity period. While the first ANDA filer enjoys the exclusive right to sell the only ANDA-approved generic product during these six months, the prices at which it may do so are lowered by price competition from authorized generics. Drug

[7] IMS Consulting, Assessment of Authorized Generics in the U.S., Spring 2006.

[8] Hassett, K. A. and R. J. Shapiro, "The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals," *Sonecon*, May 2007, p. 3.

[9] Berndt, E., R. Mortimer, A. Bhattacharjya, A. Parece and E. Tuttle, "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," *Health Affairs*, v. 26, n. 3, May/June 2007, p. 796.

[10] FTC Study, Federal Trade Commission, "Authorized Generics: An Interim Report," June 2009.

purchasers are intended to, and do indeed benefit from, lower prices caused by authorized generic entry during and after the six month exclusivity.

V. FACTS

A. Wyeth Obtains the Original Compound Patent for Effexor

62. On August 13, 1985, the PTO issued a patent for the compound venlafaxine hydrochloride ("venlafaxine"), U.S. Patent No. 4,535,186 (the "Husbands patent"). The inventors G.E. Morris Husbands and others assigned the Husbands patent to American Home Products – later Wyeth.

63. Eight years later in December of 1993, FDA approved Wyeth's NDA for Effexor, an antidepressant whose active pharmaceutical ingredient is venlafaxine. Effexor is a tablet that dissolves rapidly, resulting in a rapid increase in blood plasma levels of venlafaxine shortly after administration. Compounds with such rapid dissolution profiles are referred to as "instant release" formulations. Levels of venlafaxine in the blood decrease over time, reaching sub-therapeutic levels in about twelve hours. Effexor is thus usually taken twice a day.

64. The Husbands patent protected venlafaxine generally, and thus it protected any kind of Wyeth venlafaxine products from generic competition before June 13, 2008. (The patent would have expired much earlier than 2008, but Wyeth received a significant extension to reflect the time it took the FDA to approve its NDA for Effexor and an additional six month extension for having conducted pediatric studies).

65. As a result, Wyeth had market exclusivity for venlafaxine products – whether instant release or extended release – for 14 ½ years. This lawful period of market exclusivity would enable Wyeth to market its venlafaxine products – both Effexor and Effexor XR – without generic competition, resulting in huge sales and profits to Wyeth. But the *quid pro quo* of the patent laws is that after this period of market exclusivity expires, generic companies

are permitted to launch competing products, thus dramatically lowering prices to the benefit of American purchasers.

B. Wyeth Develops Extended Release Venlafaxine Products

66. Pharmaceutical development typically involves (i) the development of a pharmaceutical formulation, (ii) clinical testing of the formulation, and (iii) seeking patent protection. During the early 1990's, Wyeth engaged in these activities in order to develop an extended release version for venlafaxine hydrochloride. A description of those efforts sets the stage for Wyeth's 1996 filing of the first patent application that gives rise to the fraudulent patents, sham infringement litigations, and illegal cooperation agreements alleged in this complaint to have blocked generic competition unlawfully.

1. Wyeth Develops Spheroid Encapsulated Extended Release Venlafaxine.

67. In 1991, the well-known drawbacks associated with immediate release dosage forms (primarily the need to take medication multiple times a day) prompted Wyeth's marketing department to request development of an extended release version of venlafaxine. Early trials with instant release venlafaxine showed that some patients who took Effexor (instant release) reported experiencing negative side effects such as nausea and vomiting. In theory, these adverse symptoms could be attributed to the spikes in the amount of active ingredient in a patient's blood plasma associated with taking multiple doses of a drug.

68. At this time, it was well-known that controlling the release of a drug (*i.e.*, smoothing out the release of the drug in the body over a full day) might avoid peaks in blood plasma levels experienced when a drug is taken multiple times during a day; again, in theory, this might lessen negative side effects associated with unstable plasma levels.

69. Extended release formulation techniques were known in the art since at least the 1950s, and were commonly taught in pharmacy schools for use with a wide variety of active ingredients. By the early 1990s, methods for achieving sustained or extended release of the active ingredient in pharmaceuticals were well known in the drug industry. It was common knowledge that the rate of drug release from solid dosage forms may be extended by (a) modifying drug dissolution by controlling access of biologic fluids to the drug through use of barrier coatings, (b) controlling drug diffusion rates from dosage forms, and (c) chemical reaction or interaction between a drug substance or its pharmaceutical barrier and site-specific biologic fluids. These methods incorporate the use of coated beads, granules, and microspheres; micro-encapsulated drugs; sustained-release, extended-release, timed-release, controlled-release, or continuous-release tablets or capsules; or embedding the drugs in slowly eroding or hydrophilic matrix systems.

70. A group of Wyeth chemists from the upstate New York area initially attempted to create an extended release venlafaxine formulation using hydrogel tablet technology (where the active ingredient is combined with cellulose ethers and then compressed into a tablet). Inventor Deborah M. Sherman had previous experience with this approach, and in the second half of 1991 set out to make an extended release hydrogel tablet containing venlafaxine. But by December of that year, Wyeth abandoned its hydrogel approach because the tablets were dissolving too rapidly.

71. Wyeth then turned to two other strategies: (i) in-house development using a conventional coated spheroid approach for active ingredients that are highly soluble, and (ii) a business venture with Alza, a pharmaceutical formulation company specializing in extended

release technology and having an available "OROS" technology that might be used to extend the release of venlafaxine.

72. As to its in-house development using the proven coated spheroid approach, Wyeth looked to its prior experience with extending the release of a similar chemical, propranolol (marketed as Inderal). Inderal LA, a "long acting" or extended release product, had been formulated well over a decade earlier and received FDA marketing approval in April 1983.

73. The Inderal LA approach to extending the release of an active ingredient was a conventional approach; the active ingredient is mixed with off-the-shelf binding agents (microcrystalline cellulose ["MCC"] and hydroxypropylmethylcellulose ["HPMC"]) to form an extrudable plastic mass from which small diameter (e.g., 1 mm) cylinders of the drug/matrix are chopped and transformed into spheroids using standard spheronization equipment. After drying, the spheroids can be film-coated with off-the-shelf cellulose products (ethylcellulose ["EC"] and HPMC) to retard dissolution. Finally, gelatin capsules are filled with the spheroids in the quantity needed for the therapeutic effect.

74. The Inderal LA formulation had been patented long ago in McAinsh *et als*., U.S. patent number 4,138,475 (the "McAinsh patent"), which taught the use of a hard gelatin capsule comprised of spheroids film-coated by a mixture of off-the-shelf EC and HPMC. Thus, this conventional approach to extending the release of a drug was prior art in the early 1990s (when extended release venlafaxine products were being developed and Wyeth was seeking additional patent protection for Effexor XR).

75. The Effexor XR inventors implemented the coated spheroid approach simply by substituting venlafaxine for the propranolol in Wyeth's Inderal LA formulation. Put differently, Wyeth used the *same off-the-shelf excipients, methodology and spheronization machine* used to

make extended release propronalol -- a film-coated spheroid formulation composed of a therapeutically effective amount of the active ingredient in spheroids (comprised of venlafaxine hydrochloride, MCC, and, optionally, HPMC) coated with a mixture of EC and HPMC.

76. Of course, Wyeth expected that the coated spheroid approach would succeed even before lab work began. The known physical, chemical, and pharmacokinetic properties of venlafaxine and propranolol were sufficiently similar for these purposes that Wyeth was confident the extended release formulation of venlafaxine would be successful. Richard DeNeale, who was managing the extended release venlafaxine project, wrote at the time "chances of success with the spheroid approach are high."

77. In 1992, within only six months or so of implementing the spheroid approach, Wyeth deemed the approach successful.

2. Alza's Development of an Osmotic Shell Extended Release Venlafaxine.

78. Meanwhile, the second strategy of using Alza's OROS technology was also being pursued. In 1992, Wyeth entered into a cooperation agreement with Alza to develop an extended release formulation of venlafaxine hydrochloride using Alza's proprietary drug delivery system. The collaboration agreement granted Alza ownership rights in any information generated or acquired during the collaboration, and the patents resulting from the collaboration. Alza also retained the right to use, disclose, and license information from the collaboration to third parties. Both Alza and Wyeth knew they were each simultaneously, developing an extended release version of venlafaxine.

79. Alza sought to use its OROS technology to extend or control the release of many drug products. Basically, the formulation uses a largely insoluble shell having an exit port that is partially permeable to surrounding water or biological fluids but largely impermeable to the

active ingredient contained inside the shell. Once swallowed, osmotic action over an extended period of time permits a controlled release of the active ingredient into the bloodstream.

80. By the end of 1992, Alza (using its osmotic approach from the OROS technology) was, like Wyeth, also successful in developing an extended release formulation of venlafaxine.

81. Wyeth then had available to it two formulations of extended release venlafaxine. It chose to pursue its own, encapsulated spheroid approach.

3. Clinical Studies for Wyeth's Extended Release Formulation.

82. Following development of the encapsulated spheroid extended release venlafaxine, Wyeth conducted clinical studies to establish the efficacy and safety of its new formulation. In some studies, Wyeth compared the extended release formulation of venlafaxine to the instant release formulation; in others, it compared the extended release to placebo. While the studies established the FDA minima of efficacy as compared to a placebo, the studies failed to establish any statistically significant improvement of the extended release over the instant release with respect to side effects such as nausea. The product might gain FDA marketing approval (and thus provide the convenience of once-a-day dosing), but Wyeth could not truthfully claim there was any valid scientific basis for claiming that the extended release version reduced side effects when compared to the instant release.

4. Wyeth's Early 1990s Efforts to Get Further Patent Protection for Venlafaxine.

83. In addition to clinical testing, Wyeth began some early efforts to secure further patent protection for venlafaxine. In June of 1993, a different group of Wyeth employees (clinicians based in eastern Pennsylvania) filed a patent application seeking a method-of-use patent for using venlafaxine for an eclectic mix of medical conditions. The application claimed as the "invention … a method of treating obesity, generalized anxiety disorder, post-traumatic

stress disorder, late luteal phase disphoric disorder (premenstrual syndrome), attention deficient disorder, with and without hyperactivity, Gilles de la Tourette syndrome, bulimia nervosa or Shy Dragger Syndrome…by administering…an effective amount of [venlafaxine]." It did not seek protection for any specific formulation of venlafaxine.

84. Because it was widely known that instant release venlafaxine would need to be dosed multiple times daily (with the associated inconvenience and potential side effects from spiking blood plasma levels), this group of Wyeth inventors described "sustained release compositions" of venlafaxine as a likely favored form of administering venlafaxine.

85. After abandoning the original application, in January of 1995, Wyeth (through this group of Wyeth employees) filed a series of continuation applications. These applications reiterated that "sustained release compositions" of venlafaxine were the likely favored form of administering venlafaxine. (Eventually, these applications led to a few method-of-use patents for specific, medical conditions).

86. Also in January of 1995, some of the same group of Eastern Pennsylvania-based Wyeth employees filed patent application no. 08/380,093, (the "Upton application"). The Upton application sought a method-of-use patent for using venlafaxine to treat hypothalamic menopause in non-depressed women. It did not seek approval of any formulations of venlafaxine. But, as was the case with the prior method-of-use application for a range of medical conditions, the specification here again disclosed a "sustained oral administration form or time-release form [of venlafaxine], which may be used to spread the dosage over time, such as for once-a-day applications."

87. On April 9, 1996, the Upton application issued as U.S. Patent No. 5,506,270 (the "Upton patent") and was later assigned to Wyeth. The Upton patent contained the same

reference to sustained and time release forms of venlafaxine to spread the dosage over time as the proposed specification at column 5, lines 23-27:

> It is understood that … this invention is intended to cover any means of administration to a patient of an active amount of the compounds listed above in the treatment of hypothalamic amenorrhea. Such administrations may also be provided in a bolus form, intermittent-release form, *sustained oral administration form or time-release form, which may be used to spread the dosage over time, such as for once-a-day applications.*

5. Alza's Early 1990s Efforts to Secure Patent Protection.

88. In the early 1990s, Alza also sought patent protection for its extended release osmotic approach for venlafaxine. On May 27, 1993, Alza filed patent application U.S. Serial No. 08/068,480, listing inventors Edgren, *et al.* (the "Edgren application"). The Edgren application eventually matured into U.S. Patent No. 6, 440,457 on August 27, 2002.

89. On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the " '589 PCT application"). The '589 PCT application claims priority to the Edgren application and discloses to the public all features of the Edgren application.

90. The '589 PCT application discloses the once-a-day venlafaxine extended release osmotic formulation (in various iterations) developed by Alza in 1992 (along with methods for the administration of venlafaxine extended release formulations, and the hours required for *in vitro* dissolution). But Alza's '589 PCT application *also* describes, repeatedly, the broader notion that the use of extended release venlafaxine would reduce the daily spiking in blood plasma levels that result from multiple daily usage of venlafaxine. And it discloses the notion that extending the release may (theoretically) reduce side effects sometimes thought to be caused by daily spiking for multiple daily doses.

91. For example, Alza explained in the '589 PCT application that conventional instant release formulations result in "large peaks and valleys … in the drug blood levels." The applicants stated that there was a "need for a controlled-release dosage form that can administer the drug at a controlled rate over an extended time to provide constant therapy and thereby eliminate the need for multiple dosing." The Alza formulations sought to "provide a drug delivery controlled release system that can deliver a drug for maintaining constant drug levels in the blood, thereby functioning as a controlled release system." Alza further sought "to provide a once a day controlled release dosage form to deliver [venlafaxine hydrochloride] orally to a patient in need of therapy[,]" and "to provide a method for administering [venlafaxine hydrochloride] in a therapeutic range while simultaneously avoiding a toxic range[.]"

92. The '589 PCT application disclosed venlafaxine hydrochloride specifically as the antidepressant pharmaceutical ingredient. The formulations were to be administered once-a-day in a single dose over a twenty-four hour period. The '589 PCT application indicates that the dosage form successfully maintained constant drug levels in the blood by virtue of its extended release properties.

93. While the '589 PCT and Edgren applications do not report peak blood plasma levels, minimization of the troughs and peaks of blood plasma levels are at the core of the extended release formulations disclosed in the '589 PCT application and the Edgren application. The notion that extending the release of venlafaxine over a 24 hour period would be a method to eliminate peaks and valleys in blood plasma concentration, and that (in theory) might reduce the toxic range inherent in blood plasma spikes, was unequivocably disclosed by Wyeth's development partner Alza in the '589 PCT application.

94. These facts set the stage for Wyeth's fraud.

B. Wyeth Fraudulently Obtains Method-of-Use Claims in Three Effexor XR Patents

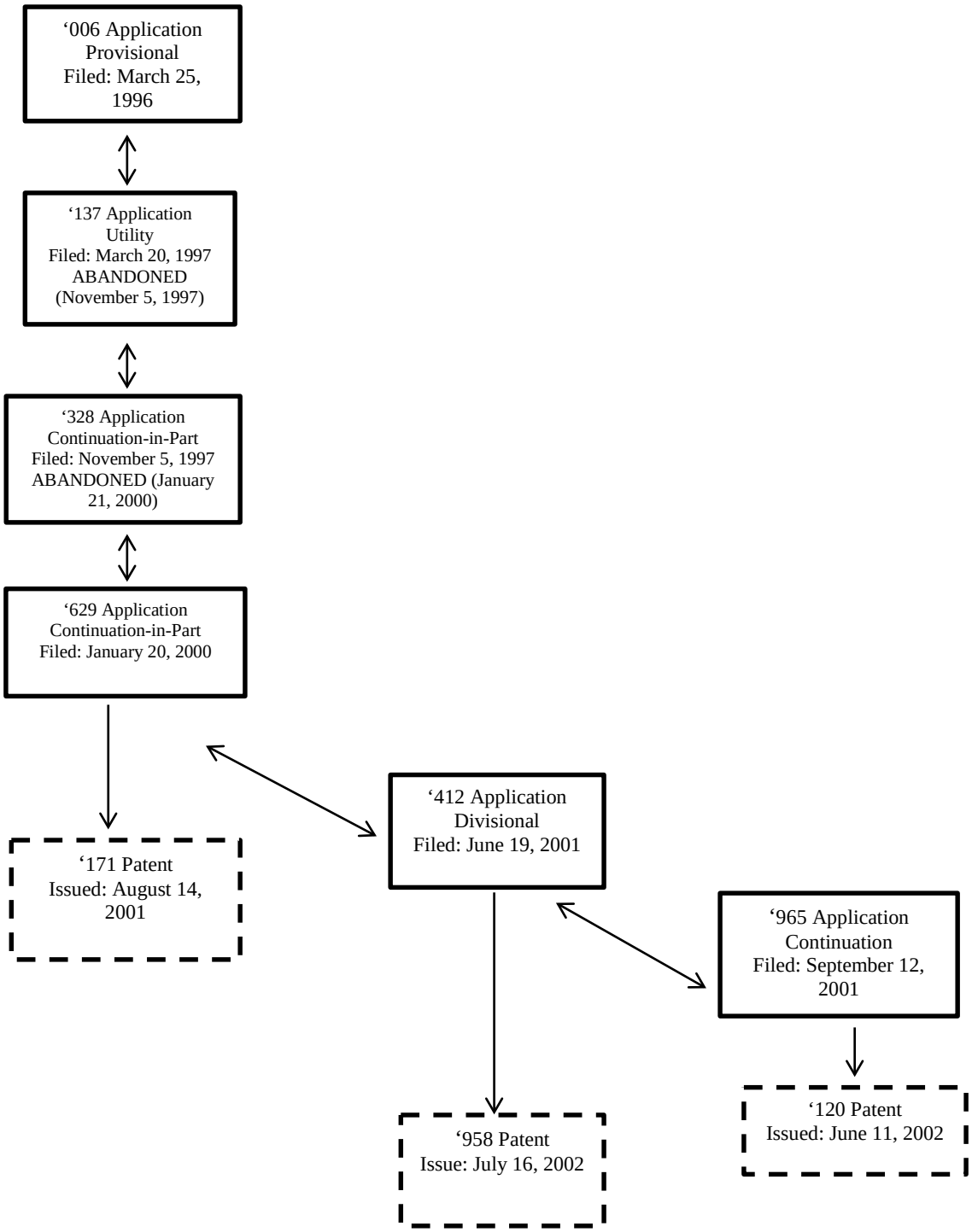
95. In the spring of 1996 – after Wyeth had applied for the Upton patent, after Alza's '589 PCT application had been published, and after Wyeth had created extended release venlafaxine by using the Inderal LA approach – Wyeth was gearing up to seek FDA approval for its extended release venlafaxine product (using the film-coated spheroid approach). Although the original Husbands patent (as extended for the time Wyeth spent pursuing NDA approval and pediatric studies) provided Wyeth with a total of 14 ½ years of market exclusivity for venlafaxine products, and although in 1996 *twelve years* remained on this exclusivity, Wyeth sought to extend the length of its exclusivity *even further*.

96. Beginning in March of 1996, Wyeth submitted six sequential applications that led to three patents, the '171, '958, and '120 patents, each of which contained ostensibly independent method-of-use claims. All three patents are, and have always been, unenforceable: They only issued because Wyeth defrauded the PTO. The fraudulently-obtained patents, the wrongful listing of these patents, and the filing of sham litigation related to these patents, prevented generic extended release venlafaxines from coming to market in June of 2008.

97. Two months later, on May 16, 1996, Wyeth sought FDA approval to sell an encapsulated extended release formulation of venlafaxine hydrochloride called Effexor XR. On October 20, 1997, the FDA approved Wyeth's NDA for Effexor XR. Effexor XR is typically taken once a day.

98. A technical summary of the family history of the patents follows. Wyeth's fraud in securing these patents is then described in detail.

1. The Application History of the Invalid and Unenforceable '171, '958, and '120 Patents



a) Wyeth's Original '006 Application

99. On March 25, 1996, the Wyeth applicants filed a provisional utility patent application, No. 60/014,006 (the " '006 application") with the PTO. A utility patent application seeks to protect a new, useful, or nonobvious process or composition. Provisional patent applications require only a brief written description of the claimed subject matter. Inventors must file a non-provisional application with formal claims within one year. Filing a provisional application essentially allows an inventor to establish a date of invention one full year before the inventor actually submits evidence of his invention's patentability.

b) Wyeth's '137 Application

100. Almost exactly one year after filing the provisional application, on March 20, 1997, the Wyeth applicants filed a non-provisional application, No. 08/821,137 (the " '137 application"). The '137 application claimed priority to the '006 application – meaning, the patentability of the '137 application would be evaluated as though it were filed a year earlier. The examiner required the Wyeth applicants to amend certain claims in light of prior art. On August 5, 1997, the examiner issued a notice of allowance for the amended claims – meaning that the patent (with amended claims) would issue so long as Wyeth paid the necessary fee ($1290.00) within three months. Despite the notice of allowance, the Wyeth applicants abandoned the '137 application.

c) Wyeth's '328 Application

101. On November 5, 1997, the Wyeth applicants filed a continuation-in-part application, No. 08/964,328 (the "'328 application"). A continuation-in-part application repeats most of an earlier parent application but adds information that was not disclosed in the previous application. A continuation-in-part application must be filed while the earlier application is still pending.

102. The ‘328 application claimed priority to the ‘137 application and the ‘006 application. The examiner allowed some claims and rejected others in light of prior art. On February 16, 2000, the Wyeth applicants abandoned the ‘328 application – including the allowed claims.

d) Wyeth’s ‘629 Application and the ‘171 Patent

103. On January 20, 2000 – one month before abandoning the ‘328 application – the Wyeth applicants filed a continuation-in-part application, No. 09/488,629 (the “ ‘629 application”) that claimed priority to the ‘328 application, the ‘137 application, and the ‘006 application. The examiner allowed some claims and rejected others. The Wyeth applicants canceled one claim, amended other claims, and added new claims. The examiner allowed the claims (as amended).

104. On August 14, 2001, the ‘629 Application issued as U.S. Patent No. 6,274,171 B1 (the “ ‘171 patent”). The ‘171 patent contains 25 claims in total, including claims for (i) an extended release form of venlafaxine hydrochloride with spheroids, (ii) method-of-use claims for decreasing the incidence of nausea and vomiting, and (iii) method-of-use claims for minimizing the troughs and peaks in drug concentration in a patient’s blood plasma. The ‘171 patent expires on March 20, 2017. The ‘171 patent is assigned to Wyeth.

e) Wyeth’s ‘412 Application and the ‘958 Patent

105. On June 19, 2001 – two months prior to the issuance of the ‘171 patent – the Wyeth applicants filed a divisional application, No. 09/884,412 (the “ ‘412 application”). A divisional application is an application for an independent or distinct invention disclosing and claiming (only) a portion of the subject matter disclosed in an earlier application. The ‘412 application claimed priority to the ‘629 application (that resulted in the ‘171 Patent), the ‘328 application, the ‘137 application, and the ‘006 application. The examiner rejected some claims

and allowed others. The Wyeth applicants then canceled one claim and added new claims that were substantially similar to claims issued in the '171 patent.

106. On July 16, 2002, the '412 application issued as U.S. Patent No. 6,419,958 B2 (the " '958 patent"). The '958 patent includes claims for (i) methods of use to decrease the incidence of nausea and vomiting and (ii) methods of use for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. The '958 patent included a terminal disclaimer that Wyeth did not seek an additional time period of patent protection beyond that afforded by the '171 patent – that is, through March 20, 2017. The '958 patent is assigned to Wyeth.

f) Wyeth's '965 Application and the '120 Patent

107. On September 12, 2001, Wyeth filed a continuation application, No. 09/950,965 (the " '965 application") that claimed priority to'412 application (which resulted in the '958 patent), the '629 application (which resulted in the '171 patent), the '328 application, the '137 application, and the '006 application. The examiner rejected some claims and allowed others. Wyeth amended some claims to overcome the rejections. The examiner allowed the amended claims.

108. On June 11, 2002, the '965 application issued as U.S. Patent No. 6,403,120 B1 (the " '120 patent"). The '120 patent contains 14 claims, all reciting a method of use for reducing the incidence of nausea and vomiting. The '120 patent also expires on March 20, 2017. The '120 patent is assigned to Wyeth.

1. The Prior Rejection Invalidity and Fraud: Wyeth Failed to Disclose a Previous Examiner's Rejection of Independent Method-of-Use Claims

a. Wyeth Filed Patent Applications For Formulations Claims That Also Include Two Method-of-Use Claims

109. In late 1995 or early 1996, the PTO notified Wyeth that the Upton application (*i.e.*, the patent application for a method to treat menopause in non-depressed women with

venlafaxine) would soon issue as a patent. Wyeth knew that particular disclosures that would appear in this patent – those describing extended release venlafaxine as a method to smooth the dosage over time – would be prior art relevant to later patent applications seeking to claim as a new invention the use of extending the release of venlafaxine as a method to control dose rates.

110. This presented an immediate problem for Wyeth — because the Upton patent disclosed once a day venlafaxine formulations that "spread the dosage over time," any later claim for a broad method-of-use patent for extended release venlafaxine would be precluded. To address this, Wyeth rushed to file a provisional application that included nausea/vomiting claims and "troughs and peaks" claims to avoid the Upton Patent standing as prior art to future extended release venlafaxine claims.

111. On March 25, 1996, the Wyeth applicants filed the '006 provisional application, the first in the family of applications involved in this case.

112. The '006 application is generally a *formulation* application. The title is "Extended Release Formulation." The abstract describes the "invention [as] a 24 hour extended release dosage *formulation*…." The background of the invention compares hydrogel tablet technology formulations as compared to encapsulated drug formulations. The brief description of the invention describes the "invention [as] an extended release (ER), encapsulated *formulation* containing venlafaxine hydrochloride …." The detailed description of the invention describes the "extended release *formulations* of this invention" as being comprised of venlafaxine "in add mixture with [MC] and [HPMC]." The four examples of the invention describe four formulations all using the encapsulated spheroid approach in which venlafaxine is mixed with MC and HPMC, and then coated with a combination of EC and HPMC. Of the ten claims set forth in the '006 application, the first eight claims are expressly formulation and composition

claims describing, in various ways, the use of spheroids comprised of venlafaxine, MC and HPMC, coated by a mixture of EC and HPMC.

113. After having claimed extended release formulation approaches set forth in the prior eight claims, the '006 application then set forth the following two claims:

> 9. *A method* of providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis *which comprises* administering orally to a patient in need of thereof, *an encapsulated, extended release formulation that* provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as to the active ingredient. (emphasis added)
>
> 10. *A method* for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses *which comprises* administering orally to a patient in need thereof, *an encapsulated extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as to the active ingredient. (emphasis added)

114. On their face, and out of context, interpretation of these claims can go in two, wildly different directions.

115. On the one hand, the claim language "encapsulated extended release formulation" might be interpreted in the context of the film-coated spheroid formulation that had been developed by the Wyeth formulators working in upstate New York. The claims would describe a method of using the particular encapsulated formulation set out in the patent specification (and elsewhere) as a means to eliminate peaks and troughs in blood plasma concentration and to diminish nausea and vomiting. An interpretation in this direction defines the method-of-use invention as limited to the new encapsulated spheroid formulation of the old venlafaxine product that slows the release of the drug. Under this interpretation, the specific spheroid formulation and the method of using it might seemingly be patentable by the PTO given the specificity of the claims (although even these formulation claims were obvious given knowledge of spheroid

formulation for substantially similar chemicals), and the patent would seemingly provide enough information as to how to make the product (in patent terms, meeting the "enablement" requirement that the patent teach others how to make the invention). But as so limited, the interpretation greatly reduces the ability of Wyeth to block potential generic entry because future generic companies could rather easily design a different extended release formulation.

116. On the other hand, the claim language "encapsulated extended release formulation" might be interpreted as relating to a method of using nearly *any* "extended release formulation" as a means to eliminate peaks and troughs in blood plasma concentration and to diminish nausea and vomiting. An interpretation in this direction would seek to have the asserted claims construed to cover not only the formulations that these Wyeth formulators developed and described in this patent application, but also nearly *every* kind of formulation of venlafaxine that allows for delayed release. A patent with such a broad interpretation would not be valid or enforceable because the notion that extending the release of venlafaxine will eliminate peaks and valleys in blood plasma levels is a pharmacologic tautology. Other reasons for obviousness were (and are) that (i) it would be invalid as obvious, as a method to use extended release venlafaxine to smooth out the dosage over time was already well known in the industry and patent literature, (ii) the "invention" was already disclosed in the Upton patent and Alza's '589 application, (iii) the invention would not be "enabled" because it arguably only taught one way to reduce it to practice (not the limitless ways the broadly interpreted language would claim), and (iv) these chemists had only invented a particular spheroid formulation, not the general notion that extended release venlafaxine of any stripe diminishes peaks and valleys in dosage over time.

117. Nevertheless, once armed with a patent containing claim language capable of this kind of wildly different interpretation, the mere ability to argue for a broad interpretation would enable the patent holder to bring a (sham) lawsuit against almost any potential generic entrant. The holder could then use the regulatory mechanisms to automatically delay generic approval, and wait for a federal court (if given the opportunity) to sort out the inevitable invalidity or unenforceability of the method-of-use claims. The mere existence of claims so framed, even when known by the holder to be flatly invalid and unenforceable, would equip the holder with a sweeping practical power to delay generic competition.

118. Following the filing of the '006 application, in April of 1996 the PTO issued the Upton patent. This prior art would render broad method-of-use claims related to spreading the dose over time (such as once-a-day dosing) and obvious consequences of spreading the dose over time (such as minimizing the "troughs and peaks" of instant release venlafaxine, or hypothesized reduction in related side effects) unpatentable.

g) Examiner Hulina Rejected Wyeth's Independent Method-of-Use Claims for an Extended Release Venlafaxine in Light of the Upton Patent

119. On March 20, 1997 (shortly within a year of filing the provisional '006 application), the Wyeth applicants filed the '137 application. The '137 application was assigned to Examiner Amy Hulina, and claimed priority to the '006 application.

120. The '137 application was virtually identical to the '006 in all respects, setting forth the Wyeth-developed, encapsulated film-coated spheroid formulation to extend the release of venlafaxine. The '137 application also set forth the same eight formulation claims as the '006 application, along with the two method-of-use claims.

121. Claim 1 recited an extended release formulation of venlafaxine hydrochloride with spheroids:

> 1. An encapsulated, *extended release formulation* of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of *spheroids* comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropylmethylcellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.[11]

122. Claim 9 recited a method-of-use claim for reducing incidences of nausea and vomiting associated with venlafaxine:

> 9. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with diminished incidences of nausea and emesis which comprises* administering orally to a patient in need thereof, *an encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

123. Claim 10 recited a method-of-use claim for reducing the disparities in concentration of venlafaxine in a patient's blood serum:

> 10. A *method* for *eliminating the troughs and peaks of drug concentration in a patient's blood plasma* attending the therapeutic metabolism of plural daily doses of *which comprises* administering orally to a patient in need thereof, *an encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

124. In signing the '137 application, the Wyeth applicants acknowledged their duty to disclose all information material to the application.

125. On July 10, 1997, the Wyeth applicants submitted an informational disclosure statement (an "IDS") listing five U.S. patents, no foreign patents, and no other publications. Wyeth did not list the original Effexor compound patent (Husbands) on the IDS, but referenced it in the specification. Examiner Hulina considered all 5 references reported by Wyeth.

[11] Italics appearing in quotes from Wyeth's patent applications and patent specifications has been added for emphasis.

126. The Wyeth applicants *did not list or otherwise disclose the Upton patent, i.e.*, the patent held by Wyeth itself, which had issued in the past year, that was for the same venlafaxine drug, and that already disclosed extended release venlafaxine as a means to spread the dosage over time. The Wyeth applicants also *did not list or otherwise disclose the '589 PCT application, i.e.*, the patent held by Alza, Wyeth's own business partner, for the development of extended release venlafaxine.

127. Examiner Hulina discovered Wyeth's Upton patent in performing her own prior art search.

128. During a telephone interview on July 30, 1997, Examiner Hulina informed Wyeth attorney Boswell that claims 9 and 10 (the two method-of-use claims for nausea/vomiting and "troughs and peaks") were not patentable as independent claims in light of the disclosure of extended release formulations of venlafaxine in the Upton patent. She further informed Wyeth that these method-of-use claims would *only* be patentable if Wyeth amended them to depend on the particular formulation of extended release venlafaxine recited in claim 1. In other words, Examiner Hulina had picked up on the possibly broad language in the method-of-use claims that could be interpreted broadly, and insisted that those claims be limited to the specific encapsulated spheroid formulation developed by Wyeth.

129. The Wyeth applicants had hoped to patent independent method-of-use claims, claims unassociated with a particular formulation of extended release venlafaxine, in order to maximize market exclusivity for extended release venlafaxine. Independent method-of-use claims could be asserted against any generic manufacturer that attempted to market any formulation of extended release venlafaxine. Dependent method-of-use claims could only be asserted against a generic manufacturer that happened to be using the same Wyeth formulation of

extended release venlafaxine. Independent method-of-use claims would provide further impediments to generic manufacturers and could translate into many millions more in profit to Wyeth.

130. The Wyeth applicants did not challenge Examiner Hulina's conclusion that claims 9 and 10 were unpatentable as independent claims. Rather, Wyeth attorney Boswell *agreed* with Examiner Hulina's conclusion by authorizing the examiner to amend the method-of-use claims in order to avoid rejection. An examiner's amendment, authorized by attorney Boswell, changed Claims 9 and 10 from independent claims to dependent claims, thereby limiting the method-of-use claims to the specific extended release formulation of venlafaxine hydrochloride recited in claim 1 of the application. This acknowledged that stand alone method-of-use claims were not patentable in light of the Upton patent.

131. On August 5, 1997, Examiner Hulina issued a notice of allowance for the two amended, now *dependent*, method-of-use claims; these method-of-use claims, now tethered to the specific formulation, were patentable because "[t]he prior art does not teach or suggest the specific extended release claim *formulation* according to claim 1" (emphasis added). The examiner also allowed the seven remaining formulation claims that variously described the encapsulated film-coated spheroid extended release venlafaxine invention, including the basic Claim 1 that simply described encapsulated spheroids using any amounts of venlafaxine, MCC and HPMC coated with any amounts of EC and HPMC.

132. The allowance notice indicated that if Wyeth believed the amendments (to which Wyeth had already agreed with the PTO) were unacceptable, Wyeth should file an amendment. It did not do so.

133. At this time, Wyeth could have finished the process, paid the issue fee by early November 1997 (three months following mailing of allowance), and caused the patent to issue. But doing so would not accomplish Wyeth's true goal – to use this formulation patent application tree as a Trojan horse to obtain method-of-use claims that might be broadly interpreted as precluding all extended release venlafaxines (even if ultimately unenforceable). So the Wyeth applicants decided to abandon the '137 application – presumably in the hopes that a new application might draw a different examiner that would be unfamiliar with the Upton patent's disclosure of extended release venlafaxine and would, therefore, allow independent nausea/vomiting and "troughs and peaks" method-of-use claims.

h) Wyeth Never Disclosed that the PTO Rejected its Method-of-Use Claims For Obviousness

(1) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '328 Application

134. On November 5, 1997 – the day it abandoned the previous application – the Wyeth applicants filed the '328 continuation-in-part application that re-proposed the identical, independent method-of-use claims previously rejected (and then amended by agreement) by the previous PTO examiner.

135. The only explanation for Wyeth's choosing to abandon the prior application, and pursue this new one, is its effort to escape the prior examiner having noticed the ambiguous phrasing of the method-of-use claims. If Wyeth truly believed it was entitled to broad method-of-use claims for venlafaxine, it could have simply filed an amendment in the '137 application (as noted as an option by the examiner in the allowance) challenging the examiner's approach; Hulina's decision would be tested, and Wyeth could appeal an adverse ruling. And in so doing, Wyeth would have left intact allowances Wyeth had obtained for the seven formulation claims in the '137 application, one of which was for the basic Claim 1 to the formulation.

136. But Wyeth avoided testing its position on Hulina's rejection, and was willing to relinquish its formulation claim gains, in order to take another run at its independent method-of-use strategy.

137. By abandoning the earlier application and filing a new one, Wyeth was able to get the '328 application assigned to a different PTO examiner in a different art unit, James M. Spear in Art Unit 1615.

138. The '328 application proposed sixteen formulation claims (doubled from the original application). The title ("Extended Release Formulation"), abstract ("invention relates to a 24 hour extended release formulation"), background (discussing prior extended release formulations), brief description of the invention ("there is provided an extended release encapsulated formulation"), detailed description (discussing the "extended release formulation of the invention"), and examples are identical to the '137 application. In addition to the 16 formulation claims, the '328 application also contained two independent method-of-use claims, claims 13 and 14. These claims were nearly *identical* to the two proposed independently written method-of-use claims 9 and 10 of the '137 application: (i) claims explicitly rejected by Examiner Hulina in light of the Upton patent's reference to an extended release form of venlafaxine hydrochloride that "spread the dosage over time," (ii) claims the Wyeth applicants had agreed to amend, and (iii) claims that Examiner Hulina had only allowed once amended (to make dependent on formulation claims). The '328 application did not contain any other independent method-of-use claims.

139. In signing the '328 application, the Wyeth applicants acknowledged their duty to disclose all information material to the application. And the Wyeth applicants specifically acknowledged their duty to disclose "material information . . . which occurred between the filing

date of the prior ['137'] application and the national date . . . of this application." The Wyeth applicants had a duty to disclose fully and specifically the prior examiner's rejection of the method-of-use claims.

140. On February 9, 1998, the Wyeth applicants submitted an IDS identifying the same five U.S. Patents identified in the IDS for the '137 application. On August 13, 1998, the Wyeth applicants submitted a supplemental IDS, listing three foreign patent documents. The IDSs did not include a copy of the prior examiner's rejection, nor did they flag in any way the prior rejection. And while this time Wyeth did list the Upton patent and the '589 application, Wyeth did not explain their relevance to an application that seemingly was limited to a specific spheroid formulation (and not to an application seeking to patent what essentially amounted to a pharmacologic tautology).

141. The Wyeth applicants knew that the prior examiner had uncovered the ambiguity in the phrasing of the two method-of-use claims, and they knew that (if broadly construed) the claims would be invalid for various reasons, including obviousness – obvious because (among other things) the Upton patent and Alza's '589 application disclosed extended release venlafaxine as a method to spread the dosage over time. The Wyeth applicants knew the prior rejection was material – indeed disclosure of the rejection would immediately tip off the new examiner to Wyeth's gambit. The Wyeth applicants also knew that, in reviewing this new application, any reasonable examiner would need to know (i) that Wyeth had been prosecuting (for over a year) a patent application for a method-of-use claim for venlafaxine that might arguably be construed for a broad method to using almost any formulation of extended release venlafaxine, (ii) that a prior examiner had rejected broad method-of-use claims (requiring them to be limited to a specific formulation), and (iii) that Wyeth had *agreed* with that objection.

142. Nor did Wyeth identify to the new PTO examiner the true relevance of the Upton patent or Alza's '589 application. An examiner reviewing the '328 application might likely see it as a formulation application limited to the specific encapsulated film-coated spheroid formulation developed by Wyeth. In this event, review of the Upton patent (addressing the use of venlafaxine to treat menopause in non-depressed women) has marginal interest at best; since Upton addresses a method to treat menopause, an examiner reviewing an application for a drug formulation patent will be looking for art relating to the formulation, not a general use of extended release venlafaxine to smooth dosage over time. The Upton reference (to extending the release of a venlafaxine to smooth out the dosage over time) contained in a single sentence in the middle of a three page single-spaced specification would not be apparent or relevant to an examiner reviewing the '328 application as an application for a formulation patent.

143. After reviewing the application, Examiner Spear issued a first office action on October 14, 1998. Examiner Spear (i) found that formulation claims that quantified the amounts for the venlafaxine/MCC/HPMC spheroids, and that quantified the ratio, or amount to be used of, EC and HPMC for the film-coating, would be patentable, (ii) allowed Claim 11 because as an independent claim that quantified the amounts it was a patentable formulation, but (iii) rejected Claim 1 (and other claims that depended on it) because its general formulation claim of using any amounts of venlafaxine/MCC/HMPC spheroids film-coated with any amounts of EC/HPMC to extend the release of venlafaxine was obvious. In allowing the encapsulated extended release formulation of venlafaxine in Claim 11, the examiner also allowed Claims 13 and 14, the two claims for methods of diminishing nausea/vomiting or eliminating troughs/peaks by "administering . . . an encapsulated extended release formulation . . .[of] venlafaxine."

144. As a result, Examiner Spear allowed the method-of-use claims (claims 13 and 14) to issue as independent claims – the very claims that Examiner Hulina had previously required Wyeth to amend to be dependent on a particular formulation. The Wyeth applicants never informed Examiner Spear that the Upton patent identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method-of-use claims unpatentable. The Wyeth applicants never disclosed to Examiner Spear that they had previously *agreed* to amend the *very same claims* to be dependent claims. And the Wyeth applicants never disclosed to Examiner Spear that a previous examiner had found the exact same claims to be unpatentable. Indeed, nothing indicates that Examiner Spear was aware of the agreement that was reached between Boswell, Wyeth's in-house counsel, and Examiner Hulina, or that Wyeth made any attempt to rescind the agreement regarding the narrowing claim amendments. Every bit of this information was material, and precisely the sort of information that Examiner Spear would have needed to know.

145. The examiner's first office action allowed three claims for a single patent. Under 35 U.S.C. §101, each separate and distinct invention must appear in separate patents. If more than one invention is described in a patent application, a restriction requirement issues and the claims to one of the inventions must be cancelled and re-filed as a separate, continuation application that would lead to a separate patent. Here, however, the first office action contained no such restriction. The action therefore shows that the three claims were considered to describe a single, distinct invention; the examiner viewed the methods of use as relating to the specific formulation claim that was also being allowed. The second examiner had not picked up on the earlier examiner's discover – that the two method-of-use claims might be read broadly to claim

methods of eliminating peaks and troughs in blood plasma levels or diminish nausea/vomiting by extending the release of venlafaxine *regardless* of the type of formulation used.

146. While the first office action achieved the Wyeth goal of obtaining allowance of the method-of-use claims, it had not achieved allowance of the general formulation Claim 1. The Wyeth applicants responded to the examiner's rejections by canceling, amending, and adding new claims. On July 21, 1999, Examiner Spear again rejected Claim 1 (and claims depending on it) for a formulation using any amounts of venlafaxine/MCC/HPMC as obvious, again stating that the Wyeth applicants' arguments to overcome the prior art were not persuasive. The Wyeth applicants responded by filing a petition for an extension of time, but never ultimately responded.

(2) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '629 Application

147. On January 20, 2000 (several weeks before abandoning the '328 application), the Wyeth applicants filed the '629 continuation-in-part application. Because it was filed before the abandonment, Wyeth's latest application was again assigned to Examiner Spear.

148. The '629 application contained a nearly identical specification to the '328 application. Claim 1, again, recited an extended release version of venlafaxine hydrochloride in spheroids that was substantially similar to the claim rejected by Examiner Spear during the prosecution of the '328 application in light of the prior art. The next nineteen claims sought iterations of the spheroid formulation. Claims 21 and 22, again, recited the same independent method-of-use claims originally presented in (rejected) claims 9 and 10 of the '137 application and (allowed but abandoned) claims 13 and 14 in the '328 application:

> 21. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, an *encapsulated, extended release formulation* that provides

> a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 22. A *method* for *eliminating the troughs and peaks of drug concentration in a patient's blood plasma* attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an *encapsulated, extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

149. The Wyeth applicants, again, never informed Examiner Spear of Examiner Hulina's rejection of the method-of-use claims. Nor did the Wyeth applicants disclose that Wyeth had agreed to amend those claims to be dependent claims in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton patent. On January 4, 2001, Examiner Spear allowed claims 21 and 22 – the two method-of-use claims.

150. The Wyeth applicants then added additional method-of-use claims 23-26. Claims 23 and 24 recite methods of use "with diminished incidence of nausea and emesis." Claims 25 and 26 recite methods of use for "eliminating the troughs and peaks of drug concentration in a patient's blood plasma." All are substantially similar to the method-of-use claims that Examiner Hulina rejected. Nonetheless, in the absence of Wyeth's disclosure of Examiner Hulina's rejection, and in failing to direct the new examiner to the meaning of the Upton patent reference to extending the release of venlafaxine to smooth the dosage over time, Examiner Spear allowed these independent method-of-use claims.

151. On August 14, 2001, the '629 application issued as the '171 patent. The '171 patent contains six independent method-of-use claims: claims 20 through 25. All recite either diminished incidences of nausea and vomiting or eliminating the troughs and peaks in a patient's blood plasma. (Due to renumbering, proposed claims 21 and 22 issued as claims 20 and 21. Proposed claims 23 through 26 issued as claims 22 through 25).

(3) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '412 Application

152. On June 19, 2001, two months before the '171 patent issued, the Wyeth applicants filed the divisional '412 application to pursue rejected Claim 1 of the '629 application. The application was again assigned to Examiner Spear.

153. The specification and claims of the '412 application were identical to those in the '629 application. The Wyeth applicants then cancelled claims 2-22 and added new, independent method-of-use claims 23 and 24:

> 23. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 24. A *method* for *eliminating the troughs and peaks of drug concentration in a patients blood plasma* attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

154. Claims 23 and 24 are substantially the same the method-of-use claims originally presented in (rejected) claims 9 and 10 of the '137 application and allowed claims 20 and 21 of the '171 patent, differing only by no longer including the word "encapsulated." The Wyeth applicants, again, never informed Examiner Spear that the Upton patent identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method-of-use claims unpatentable. The Wyeth applicants, again, never disclosed to Examiner Spear that a previous examiner determined method-of-use claims virtually identical to claims 23 and 24 were unpatentable. The Wyeth applicants, again, never disclosed that they had agreed to amend

virtually identical claims in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton patent.

155. On January 13, 2002, Examiner Spear rejected claims 23 and 24 as being unpatentable over claims 20 and 21 of the '171 Patent. The Wyeth applicants contested that claims 23 and 24 were obvious in light of the '171 patent, but filed a terminal disclaimer confirming that it did not, and would not, seek an additional time period of patent protection beyond that afforded by the '171 patent.

156. The Wyeth applicants also added claims 25 through 28, additional independent method-of-use claims. Claims 25 through 28 either recite a method-of-use "with diminished incidence of nausea and emesis" or for "eliminating the troughs and peaks of drug concentration in a patient's blood plasma." All are substantially similar to the method-of-use claims rejected by Examiner Hulina. Nonetheless, in the absence of the appropriate disclosures by Wyeth, Examiner Spear allowed claims 23 through 28.

157. On July 16, 2002, the '412 application issued as the '958 patent. The '958 patent contains six method-of-use claims: claims 1-6. All related to either diminish incidences of nausea and vomiting or eliminating the troughs and peaks in a patient's blood plasma. (Due to renumbering, proposed claims 23 and 24 issued as claims 1 and 2. Proposed claims 25 through 28 issued as claims 3 through 6.)

(4) Wyeth Did Not Disclose the Previous Examiner's Rejection in the '965 Application

158. On September 12, 2001, the Wyeth applicants filed the '965 continuation-in-part application. The '965 application was, again, assigned to Examiner Spear.

159. The '965 application contained the same specification and claims as the '412 application (and corresponding '958 patent). The Wyeth applicants canceled claims 2-22 and

added new claims 23-34. Claim 23 recited a method-of-use claim for diminished incidences of nausea and vomiting, and substantially similar to rejected claim 9 of the '137 application:

> 23. A *method* for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with *diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine of no more than 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

160. The Wyeth applicants, again, never disclosed to Examiner Spear that a previous examiner determined a claim substantially similar to claim 23 was unpatentable. The Wyeth applicants, again, never disclosed that it had agreed to amend a substantially similar claim in order to avoid a rejection over the prior art disclosed by Wyeth's own Upton patent. And the Wyeth applicants did not direct the examiner to Upton's reference to extended release venlafaxine hydrochloride.

161. Examiner Spear allowed claim 23, and objected to claims 24-34. The Wyeth applicants later amended claims 24 and 25 to depend from allowed claim 23. Examiner Spear allowed the amended claims.

162. On June 11, 2002, the '965 application issued as the '120 patent. Due to renumbering, proposed claim 23 issued as claim 1:

> 1. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with diminished incidences of nausea and emesis* which comprises administering orally to a patient in need thereof, *an extended release formulation* that provides a peak blood plasma level of venlafaxine of no more than 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

163. All other claims depended from claim 1.

i) Wyeth has previously taken the position that another examiner's rejection of an extended release venlafaxine patent in light of prior art likely invalidates a substantially similar claim.

164. In attacking competitor Alza's patent relating to extended release venlafaxine, Wyeth took the position that an examiner's rejections of substantially similar claims makes it "extremely likely" that the proffered claims will be patentable.

165. In 2006, Alza sued Wyeth for infringing its Edgren patent (the '476 patent) pertaining to extended release venlafaxine. Wyeth responded by asking the Court to stay the proceedings while the PTO conducted reexamination proceedings on the '476 patent.

166. According to Wyeth's motion for stay, Wyeth had initiated a reexamination of Alza's Edgren patent based on the fact that the PTO had rejected substantially similar claims to those included in the '476 in other patent applications bearing identical specifications in light of prior art. Wyeth claimed that it was "extremely likely" that, upon reexamination, the PTO would reject or cancel Alza's Edgren patent:

> In this motion, WYETH seeks a stay of litigation pending the outcome of a reexamination proceeding that WYETH initiated before the United States Patent and Trademark Office ("PTO") on July 28, 2006. In that proceeding, the PTO will consider the patentability of the single claim in the '457 patent over prior art known to Alza, but not considered by the PTO during the prosecution of the application lading to the '457 patent. Significantly, in two of Alza's patent applications having the identical specification as the '457 patent, the PTO-including the PTO's Board of Patent Appeals and Interferences – has rejected substantially similar claims over the same prior art that forms the basis of WYETH's Reexamination Request. Consequently, it is extremely likely that the PTO will reject Alza's '457 patent claim over the same prior art and ultimately cancel the claims under 35 U.S.C. § 307(a).

167. Elsewhere in its briefing, Wyeth similarly argued that "the rejection of substantially similar claims in related applications provides evidence that a substantial new question of patentability existed."

j) Wyeth Intentionally Committed Fraud on the PTO by Failing to Disclose Material Information

168. The prosecution history of the '137 application shows that Examiner Hulina judged the independent method-of-use claims (claims 9 and 10) unpatentable in view of the prior art taught by Wyeth's Upton patent. Claims 9 and 10 became patentable only after Wyeth amended the claims to be dependent on a particular formulation of extended release venlafaxine at the insistence of Examiner Hulina.

169. Throughout the prosecution history of the method-of-use claims in these patents (including the '328, '412, '629 and '956 applications), Wyeth repeatedly misrepresented in its PTO filings that it was providing to the new PTO examiner all material information. This, as Wyeth was well aware, was untrue. Wyeth knowingly and repeatedly witheld material information relating to Examiner Hulina's determination of unpatentability.

170. The Wyeth applicants had a duty to disclose all information material to patentability, including information that by itself renders the claims unpatentable. The Wyeth applicants failed to disclose to new Examiner Spear the contrary findings of the earlier examiner on the identical claims. Perhaps even more egregiously, the Wyeth applicants failed to disclose the basis of the earlier examiner's contrary findings – that there was a possible broad reading of these claims, and that when so read a prior art patent owned by Wyeth itself taught an extended release formulation of venlafaxine. The Wyeth applicants failed to disclose to Examiner Spear the fact that they had already agreed to narrow the scope of identical claims in order to avoid a rejection over Wyeth's own prior art patent – the Upton patent. The Wyeth applicants failed to disclose to Examiner Spear the fact that they had agreed to amend the claims to overcome the prior art reference and Examiner Hulina found the claims to be patentable once the claims were limited to the Wyeth formulation.

171. The information withheld by the Wyeth applicants was highly material. This information is of the type a reasonable examiner would want to know, as it directly impacts the patentability of the claims. But for the concealment of this information, the PTO would not have issued the method-of-use claims in the fraudulently obtained patents.

172. The Wyeth applicants withheld this material information and thereby breached their duty of disclosure to the PTO. They did so in order to avoid prior art rendering independent method-of-use claims unpatentable; that is, the Wyeth applicants sought to prosecute independent method-of-use claims that were substantially similar to the previously rejected independent method-of-use claims.

173. The Wyeth applicants withheld this material information with intent to mislead or deceive the PTO. This is the *only* plausible reason for Wyeth's actions. The only reason to not tell the second examiner about the first examiners' (authorized) amendment of the method-of-use claims and office action was the hope that the second examiner would not pick up on the fact that the method of use claims could have been read broadly – particularly in light of the fact that the first examiner actually approved Wyeth's formulation claims.

174. The Wyeth applicants failed to amend the independent method-of-use claims in accordance with Examiner Hulina's findings in the subsequent patent applications. The Wyeth applicants had multiple opportunities to amend claims during prosecution of the '171, '120, and '958 patents, and in fact did amend claims several times. But the Wyeth applicants never made the necessary amendments to overcome patent-defeating prior art on identically or substantially similar claims. They knew, of course, that doing so would prevent them from effectuating their anticompetitive scheme to delay generics by filing baseless litigation.

175. The Wyeth applicants had multiple opportunities to correct the record and bring the rejection of the claims based on the Upton Patent to the attention of Examiner Spear, yet failed to do so. The Wyeth applicants amended the claims several times in each subsequent application; Wyeth amended the specifications of two subsequent applications (the '328 application and the '629 application, which issued as the '171 patent) and amended the inventorship of the '629 application. Each filing presented an opportunity for Wyeth to correct the record, but it failed to do so.

176. Intent to deceive the PTO is the only plausible explanation for the numerous opportunities that Wyeth had to amend claims and specifications and/or bring the prior decision of unpatentability to Examiner Spear's attention. The only reasonable explanation for Wyeth's repeated pattern of nondisclosure and withholding highly material information in serial patent applications for virtually identical claims (and abandonment of those applications that no longer included ambiguous method-of-use claims) is that Wyeth meant to deceive the PTO.

177. But for this fraud on the PTO, no independent nausea/vomiting or "troughs and peaks" method-of-use claims would have issued. Specifically, Wyeth's prior rejection fraud affects claims 20 through 25 of the '171 patent and all of the claims of the '958 and '120 patents. Because Wyeth defrauded the PTO by failing to disclose the previous examiner's rejection, Wyeth is not entitled to immunity for its petitioning activities in seeking the fraudulently-obtained '171, '120, and '958 patents. In the stark light of later patent infringement litigation, all three patents would be rendered entirely invalid and unenforceable: invalid as a result of the prior art, and unenforceable as a result of Wyeth's fraud.

2. The Nausea Fraud: Wyeth Fraudulently Claimed Clinical Data Showed a Reduction in Nausea and Vomiting

a. Wyeth Claimed Effexor XR Significantly Reduced the Incidence of Nausea and Vomiting Associated with Effexor

178. In order to obtain a patent that protects a specific method of using a product, the applicants must have a legitimate basis for claiming that the method actually accomplishes what the applicants claim it accomplishes. That is, the applicants cannot just claim a method of using a pharmaceutical that reduces nausea and vomiting; applicants must have a basis for claiming that the method of use reduces nausea and vomiting *and* the method of use must actually reduce nausea and vomiting.

179. In the original '006 provisional application, the Wyeth applicants claimed its patentable invention related to a 24-hour extended release dosage formulation of venlafaxine that "provides a lower incidence of nausea and vomiting than the conventional tablets." Specifically, the Wyeth applicants told the PTO that the use of the once-a-day formulation of venlafaxine hydrochloride capsules (later marketed as Effexor XR) reduced "the level of nausea and incidence of emesis that attends the administration of multiple daily dosing." (The term 'emesis' means vomiting.)

180. In support of this statement, the Wyeth applicants claimed clinical data showed that the incidence of nausea in people taking *extended release* venlafaxine was significantly less than in patients taking *instant release* venlafaxine:

> In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. *Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.*

The Wyeth applicants made the same claim, repeating the *exact same* language, in the specifications accompanying the '137 application, the '328 application, the '629 application, the

'412 application, and the '965 application. The *exact same* language appears in the '171 patent, the '958 patent, and the '120 patent.

181. The Wyeth applicants claimed that in light of the clinical data, it was entitled to method-of-use claims for the reduction in the incidence of nausea and vomiting:

> Thus, in accordance with this use aspect of the invention there is provided *a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride* which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

The Wyeth applicants made the same claim, repeating the *exact same* language, in the specifications accompanying the '137 application, the '328 application, the '629 application, the '412 application, and the '965 application. The *exact same* language appears in the specifications for the '171, '958, and '120 issued patents.

182. The Wyeth applicants did not provide the PTO with any other evidence of Effexor XR's ability to reduce the incidence of nausea or vomiting. Wyeth did not disclose to the PTO which studies showed the reported reductions. Nor did Wyeth disclose to the PTO the raw data collected in these studies. Wyeth's sole support for its method-of-use claims for the reduction of nausea and vomiting was the express representation that two eight-week studies and one twelve-week clinical study showed that Effexor XR "showed a statistically significant improvement" in the incidence of nausea and vomiting over conventional Effexor.

a) The Clinical Data Did Not Show That Effexor XR Significantly Reduced the Incidence of Nausea and Vomiting

(1) None of the Three Studies Showed a Reduction in Nausea or Vomiting

183. The Wyeth applicants repeatedly told the PTO that "Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two

eight-week and one 12 week clinical studies." The Wyeth applicants first made this statement in its March 25, 1996 '006 provisional application. It was not until nine years later – four years after securing the '171 patent and in the context of patent infringement litigation with generic companies – that Wyeth first identified the "two eight week and one 12 week studies:" "600B-208-US," "600B-209-US," and "600B-367-EU," or studies 208, 209, and 367. Wyeth relied on these studies in seeking FDA approval of Effexor XR, but never identified them to the PTO.

184. Study 208 was a double-blind, flexible dose, twelve-week efficacy study of Effexor XR, Effexor, and placebo in outpatients with major depression.

185. Study 209 was a double-blind, flexible dose, eight-week study of Effexor XR and placebo in outpatients with major depression. Study 209 did not use instant release Effexor as a comparator.

186. Study 367 was a double-blind, flexible dose, eight-week efficacy study of Effexor XR, the antidepressant Paxil, and placebo in outpatients with major depression. Study 367 did not use instant release Effexor as a comparator.

187. None of these three clinical studies showed that Effexor XR had a statistically significant improvement in the incidence of nausea or vomiting over Effexor.

188. Studies 209 and 367 could not possibly have shown a reduction in nausea and vomiting over conventional venlafaxine hydrochloride (Effexor) *because they did not include a group of patients taking instant release, conventional Effexor*. Only study 208 included both patients receiving Effexor XR and patients receiving Effexor. Only study 208 could have allowed Wyeth to compare the incidence of nausea between the Effexor and Effexor XR groups.

189. But study 208 did not show a "statistically significant improvement" over Effexor. In fact, according to a published article describing the study, *the incidence of nausea*

was exactly the same in the Effexor XR and the Effexor groups: 45% of Effexor XR patients experience nausea, as compared to 45% of Effexor patients. *See* Lynn M. Cunningham et al., *Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, 9(3) ANNALS OF CLINICAL PSYCHIATRY 157 (1997) (reporting results of the venlafaxine XR 208 study group). Wyeth never disclosed this article, (published years before the '120, '171, and '958 patents issued) or its conclusions about rates of nausea to the PTO in any of its patent applications.

190. Study 208 also suffered from serious data corruption. The principal investigator of one of the study sites, Bruce Diamond Ph.D., and one of his sub-investigators, Richard Borison, M.D., Ph.D., were indicted for diversion of research funds on February 19, 1997, almost a full year after Wyeth claimed clinical data showed a significant reduction in the incidence of nausea with Effexor XR based in part on the results of study 208. Upon learning of these indictments, the FDA noted that the data from study 208 was "of uncertain reliability" and asked Wyeth to reanalyze the data from study 208, excluding the data from the corrupted site. Wyeth provided a reanalyzed data to the FDA. Wyeth never informed the PTO about the corrupted data. Wyeth never provided reanalyzed data – or any data from study 208 – to the PTO.

191. In September 2004, Wyeth submitted a further revised version of the final clinical report for the 208 Study. Although characterized as "minor corrections," the revisions included two revised analyses of the data on nausea. These revised analyses were never submitted to the PTO.

(2) Pooled Study Data Did Not Show a Reduction in Nausea or Vomiting

192. The Wyeth applicants told the PTO that *each* of the three studies *independently* showed a statistically significant improvement in the incidence of nausea and vomiting. Wyeth later claimed, in litigation with the generics, that it had not intended to claim the studies independently showed these results, but that "pooled" data showed the professed reduction in nausea and vomiting. But even if the data from all three studies were combined, or "pooled," it does not show a statistically significant reduction in the incidence of nausea or vomiting.

193. First, because two of the studies did not include an Effexor treatment group, at best the data from the Effexor XR treatment groups in studies 208, 209, and 367 could be pooled and compared only to the conventional Effexor treatment group in study 208. This type of comparison is scientifically unacceptable, and cannot support a claim that one drug has fewer instances of side effects than another drug. The combination or "pooling" of patient data from studies 208, 209, and 367 would be statistically biased, and thus an improper basis for reaching a conclusion that there is a statistically significant improvement in nausea by patients taking Effexor XR as compared to patients taking instant release Effexor

194. Second, even if this incorrect pooling is done, it does not show a statistically significant difference in nausea and vomiting.

195. Throughout the time that Wyeth prosecuted the fraudulently-obtained patents, Wyeth had not "pooled" the data from the 208, 209, and 367 studies. A decade later, during patent infringement litigation with the generics, Wyeth tried to cover its tracks by having 30(b)(6) deposition witnesses (Dr. Mangano and Dr. Alaburda) present new, never-before seen, elaborate calculations and permutations of the original clinical study data that purportedly showed a diminished incidence of nausea and vomiting. These calculations were done ten years

after the clinical studies were completed and nine years after the Wyeth applicants told the PTO that extended release venlafaxine reduced the incidence of nausea and vomiting.

196. Drs. Mangano and Alaburda testified that, according to yet another Wyeth employee, Wilfredo Ortega-Leone, the Wyeth applicants' claim that Effexor XR reduced the incidence of nausea was based on pooling the nausea data for the Effexor XR treatment groups in studies 208, 209, and 267 and comparing that data to nausea data for conventional Effexor treatment groups in entirely different (undisclosed) studies. Comparing different treatment groups from entirely different studies is wholly inappropriate, statistically biased, and is not a legitimate basis for claiming that one drug has fewer side effects than another drug. And, just as importantly, Wyeth never disclosed its statistical sleight-of-hand to the PTO.

197. In fact, the only reason that pooled Effexor XR data might possibly have shown a reduction in nausea (as compared to unrelated study data for conventional Effexor) is because it included the results of study 367. Study 367 reported markedly fewer instances of nausea in the Effexor XR treatment group than were reported by the Effexor XR treatment groups in studies 208 and 209. Study 367 was conducted in Europe. Studies 208 and 209 were conducted in the United States. Using the same extended release formulation, the European population in study 367 reported a 17% incidence of nausea, while the U.S. population in study 209 reported a 36% incidence of nausea.

198. The Wyeth applicants knew, and it was well known at the time, that the European population has a significantly greater tolerance for and/or underreports side effects such as nausea and vomiting (as compared to the U.S. population). By including the European Effexor XR data, it would look like Effexor XR reduced the incidence of nausea, when the real cause of the ostensible reduction in nausea was a known population difference. The Wyeth applicants did

not disclose to the PTO that the claimed reduction in nausea and vomiting was a result of studying populations that are less likely to experience and/or report side effects.

199. Further, as the FDA confirmed when analyzing Effexor XR's efficacy, *study 367 was a complete and utter failure:* "study 367 provided no persuasive evidence of antidepressant efficacy for venlafaxine ER." The Wyeth applicants never disclosed to the PTO that study 367 failed to show that Effexor XR was effective.

(3) The FDA Refused to Pool Side Effect Data from the 208, 209, and 367 Studies

200. In applying for FDA approval of Effexor XR, Wyeth argued that the FDA should evaluate the incidence of adverse events, including nausea and vomiting, by pooling the data from studies 208, 209, and 367. The FDA disagreed.

201. On August 13, 1997, the FDA noted that "the incidence of many adverse events in the European study seemed to be substantially lower than in the two domestic studies" and determined that study 367 could not properly be included in the pooled U.S. data used to assess the adverse events associated with Effexor XR:

> The incidence of many important adverse events appeared to be lower in the European study (367) compared to both U.S. studies (208 and 209). Primarily for this reason, *study 367 was not considered poolable with studies 208 and 209 for purposes of delineating the common adverse event profile of Effexor XR.*

202. The FDA noted that including study 367's data in the pooled adverse event data would result in a marked reduction in the number of adverse events described on the drug's label. If data from studies 208, 209, and 367 were pooled, the Effexor XR label would have listed only eight common drug-related adverse events. In contrast, when only the data from studies 208 and 209 were pooled, the Effexor XR label would have listed an *additional* four common drug-related adverse events. The FDA stated that "Effexor XR is placed in a more

favorable light if [Wyeth's proposed] pool is used," and therefore refused to allow the adverse event labeling to be based on Wyeth's proposed pooling.

203. Further, the FDA ultimately permitted Wyeth to pool data from the 208 and 209 studies, but *not* for the purpose of comparing the incidence of side effects between extended release venlafaxine and instant release venlafaxine. The FDA noted that "the pool of the two domestic studies [studies 208 and 209] allows for a more conservative presentation of adverse event data in labeling and since Effexor XR will be marketing in the U.S., the pool of the two U.S. studies may be more relevant." The FDA's refusal to pool data from all three studies occurred only a year after Wyeth filed the original '006 application, well before Wyeth filed its subsequent patent applications, and almost 4 years before the first, '171, patent issued.

204. Wyeth knew that including the results of European study 367 skewed the incidence of adverse events (including nausea) because the FDA told them so at least four years before the '171 patent issued, a patent whose claims were premised on Effexor XR's reported ability to reduce the incidence of nausea experienced by patients taking instant release Effexor. Yet the Wyeth applicants never informed the PTO that the FDA refused to include the data from study 367 when analyzing the incidence of adverse events associated with Effexor XR – that is, that the FDA refused to assess the incidence of side effects by pooling the 208, 209, and 367 data.

205. The FDA-approved package insert for Effexor XR does not contain any representation that Effexor XR showed a statistically significant improvement in nausea or vomiting over Effexor, even though the package insert compares Effexor XR and Effexor as to the potential for other adverse reactions in the course of their administration.

b) Wyeth Intended for the PTO to Rely on Its Material Misrepresentations

206. The Wyeth applicants intended to deceive the PTO with their misrepresentations about nausea and vomiting. This is the only explanation for its actions.

207. The Wyeth applicants repeatedly made misrepresentations about the incidence of nausea associated with Effexor XR during the prosecution of the '137 application, the '328 application, and each of the final applications for the '171, '120, and '958 patents. The Wyeth applicants affirmatively, and repeatedly, misrepresented that they possessed three clinical studies that showed Effexor XR significantly reduced the incidence of nausea and vomiting associated with Effexor. The Wyeth applicants further affirmatively misrepresented that extended release venlafaxine greatly reduced the probability of developing nausea. Specifically, the Wyeth applicants knowingly included the following sentences in the patent specifications submitted to the PTO:

> In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.

208. The Wyeth applicants knew these representations were false. The Wyeth applicants knew the only study directly comparing Effexor XR and Effexor (study 208) did not show the claimed statistically significant improvement. The Wyeth applicants knew Wyeth was not in possession of three clinical studies that showed the claimed statistically significant improvement in nausea. The Wyeth applicants knew that two out of the three referenced studies did not even compare Effexor XR to Effexor. The Wyeth applicants knew that any claimed reduction in nausea and vomiting was a result of conducting study 367 among a population that notoriously reports fewer side effects, such as nausea and vomiting. Wyeth knew that the

claimed reduction in nausea and vomiting could only be supported, if at all, by inappropriately comparing different treatment groups across different studies. And, the Wyeth applicants knew the FDA had refused to pool the 208, 209, and 367 study data when analyzing the incidences of side effects associated with extended release venlafaxine.

209. The Wyeth applicants knew the PTO would read the patent specifications submitted with their various patent applications and thus receive their misrepresentations about Effexor XR's effectiveness in reducing nausea and vomiting and about the results of the three referenced clinical studies.

210. Each individual associated with the filing and prosecution of a patent application has a duty to disclose "all information known to that individual to be material to patentability." 37 C.F.R. § 1.56 (2000). Information is material if it establishes unpatentability, whether by itself or in combination with other information, or if it refutes or is inconsistent with a position taken by an applicant in arguing for patentability. The Wyeth applicants were aware of their individual obligations to disclose material information, and signed certifications acknowledging this duty.

211. The Wyeth applicants knew that their misrepresentations about nausea and vomiting were material. No nausea and vomiting method-of-use claims could have been patented in light of the truth: extended release venlafaxine did not meaningfully reduce the incidence of nausea and vomiting, Wyeth did not have clinical data from three studies that showed a reduction in nausea and vomiting, and pooled data from three studies did not show a reduction in nausea and vomiting.

212. The Wyeth applicants also failed to inform the examiner about the Cunningham article (reporting results from study 208) and the FDA's refusal to pool the data. Both were

material: a reasonable examiner would want to know about contradicting published materials and another federal regulatory agency's determination about pooling.

213. The Wyeth applicants knew there was a substantial likelihood the PTO would rely on their misrepresentations about nausea in evaluating their numerous nausea and vomiting method-of-use claims because the Wyeth applicants did not provide any other evidence that extended release venlafaxine reduced nausea and vomiting.

214. The PTO did, in fact, rely on the Wyeth applicants' misrepresentations. In the absence of any other basis for substantiating Wyeth's nausea and vomiting claim, the PTO relied on the singular, but oft repeated, statement that clinical studies showed Effexor XR reduced the incidence of nausea and vomiting as compared to Effexor in approving *twenty* claims that began by reciting a method of use that reduces nausea and vomiting:

> A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period *with diminished incidence of nausea and emesis* which comprises administering orally to a patient in need thereof ….

215. The nausea fraud directly affects claims 20, 22, and 23 of the '171 patent; claims 1, 3, and 4 of the '958 patent; and *all* of the claims of the '120 patent. Because Wyeth defrauded the PTO by claiming a reduction in nausea and vomiting, Wyeth is not entitled to immunity for any claimed petitioning activities in seeking or enforcing the fraudulently-obtained '171, '120, and '958 patents.

3. The Unexpected Discovery Invalidity and Fraud: Wyeth Fraudulently Claimed Extended Release Venlafaxine was "Unexpected."

216. An applicant can obtain a patent only if he is the first to invent the subject matter described in the patent application. If earlier publications or patents disclose the invention, or it can be established that someone else invented the subject matter, the invention is not patentable.

See 35 U.S.C. § 102. Prior invention of the subject matter by someone else may be demonstrated by:

- Printed publications that describe the invention, either in the U.S. or internationally, before the invention thereof by the patent applicant (35 U.S.C. § 102 (a));
- A printed publication that describes the invention, published more than one year before the patent applicant filed a patent application for it (35 U.S.C. § 102 (b));
- A U.S. patent application filed by another inventor describing the invention before the invention thereof by the patent applicant (35 U.S.C. § 102(e)(1)); and
- Evidence of earlier invention by another, including non-public disclosures (35 U.S.C. § 102 (f); *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403 (Fed. Cir. 1997)).

217. Throughout the prosecution of the '171, '120, and '958 patents, the Wyeth applicants fraudulently misrepresented Wyeth's "unexpected" discovery of an extended release venlafaxine hydrochloride capsule to the PTO. *Wyeth represented in all of its applications for the '171, '120, and '958 patents that it was "completely unexpected that an extended release formulation containing venlafaxine could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble."* The Wyeth applicants first made this representation in the provisional '006 application, filed on March 25, 1996. All of the fraudulently-obtained patents include this language.

218. But an extended release version of venlafaxine hydrochloride was not at all unexpected to Wyeth. It was predicted and known. The Wyeth applicants were aware of extended release versions of venlafaxine hydrochloride long before filing the '006 application. Wyeth long knew of the solubility of venlafaxine hydrochloride. At the time of the '006 application, Wyeth's development partner Alza had long developed an extended release venlafaxine despite known solubility of the hydrochloride. Wyeth itself had used conventional spheroid technology it had employed for Inderal LA as a predictably successful approach to

extending the release of venlafaxine. And Wyeth's own Upton patent disclosed extended release venlafaxine.

219. The Wyeth applicants had multiple opportunities to amend the specifications in its various applications to no longer assert that formulating an extended the release venlafaxine hydrochloride was surprising or unexpected, but failed to do so. Wyeth knew that by making such an amendment, it would no longer be able to claim a formulation of extended release venlafaxine. Its approach had been obvious.

a. Wyeth Did Not Disclose that it Used the Formulation of its Inderal LA Formulation to Develop Effexor XR.

220. Wyeth was selling Inderal LA years before it began its development of Effexor XR. Inderal LA is a sustained release formulation of propranolol used to treat high blood pressure.

221. Propranolol and venlafaxine have similar chemical properties: both have similar molecular weights, both are formulated using the same salt, both are readily soluble in water, and both have similar half-lives. In addition, the necessary dose required for treatment and therapeutic range for both drugs is approximately the same.

222. Because of these similarities, the Wyeth formulators used Inderal LA as a model when they set out to develop Effexor XR. After discarding the hydrogel approach, the formulators simply substituted venlafaxine for propranolol in the Inderal formulation. In developing Effexor XR, Wyeth scientists, including the named inventors of Effexor XR, used exactly the same methods used to manufacture Inderal LA but used venlafaxine instead of propranolol. They created venlafaxine spheroids using the same manufacturing methods used to create propranolol spheroids and applied exactly the same EC/HPMC solvent-based coating used to coat the propranolol spheroids. The Effexor XR inventors were able to develop the Effexor

XR formulation in the first six months of 1992 because Wyeth already created the Inderal LA formulation years earlier.

223. Notwithstanding the fact that the formulation of Effexor XR was for practical purposes the same formulation of Inderal LA (but with a different active ingredient), the Wyeth applicants failed to disclose to the PTO the facts about the simple formulation of extending the release of venlafaxine. Moreover, the inventors affirmatively misrepresented alleged factual differences between venlafaxine and propanalol, differences that were known to be immaterial for the purposes of using the spheroid approach employed here.

a) Wyeth's Failure to Disclose the Role of the Inderal LA Formulation Was Material.

224. During prosecution of Wyeth's patents, PTO Examiner Spear issued a rejection based on the patent that covers the Inderal LA product, U.S. Patent No. 4,138,475 to McAinsh (the "McAinsh patent").

225. Even after receiving express notice that the examiner viewed the propranolol formulation disclosed by the McAinsh patent to be material, Wyeth not only chose to conceal the facts of its development process, it affirmatively misled the PTO. Wyeth argued in the '328 patent application that propranolol was irrelevant because there is "a tremendous difference in the water solubilities" between propranolol and venlafaxine.

226. That Wyeth had already developed an extended release product whose active ingredient was similarly soluble to venlafaxine -- *and plugged venlafaxine into the extended release formulation of propranolol to come up with Effexor XR* -- would have been of particular importance to the examiner because the patent specifications specifically state that extended release formulations of venlafaxine were "completely unexpected" because the hydrochloride of venlafaxine was extremely water soluble.

227. The label of Inderal LA directly contradicted Wyeth's arguments that propranolol and venlafaxine had significantly different solubilities. The label showed that, like venlafaxine, propranolol was readily soluble in water and had a peak blood level that occurred in about six hours.

228. The role of Inderal LA in the development of Effexor XR and the characteristics of propranolol, including its solubility, were not disclosed in the McAinsh patent and would have been highly material to the patent examiner. Wyeth had a duty to disclose this information to the patent examiner who could not have been expected to have obtained the information himself, but properly relied upon Wyeth to comply with its duty of candor.

229. The Inderal fraud tainted the patent application process, undercut Wyeth's claim of unexpected success, and affects all claims of all three patents.

b) Wyeth Intentionally Failed to Disclose this Material Information About the Use of the Inderal LA Formulation to Develop Effexor XR.

230. In light of Examiner Spear's rejection based on the McAinsh patent, the Wyeth applicants were aware of the significance of propranolol to the prosecution of patents related to Effexor XR.

231. Instead of disclosing the role of Inderal LA in the development of Effexor XR, Attorney Seifert responded to the rejection of the '328 Application by telling the examiner that "the teaching of sustained release formulation of microcrystalline cellulose and propranolol in McAinsh et al. is not deemed sufficiently relevant to venlafaxine because the two compounds are not structurally related."

232. This statement was plainly false. The Wyeth applicants knew that the Inderal LA formulation was relevant to the patentability of Effexor XR. They used that very formulation to develop the extended release venlafaxine formulation that they sought to patent.

233. Rather than disclose the use of Inderal LA process during prosecution, Wyeth chose to disclose their dead-end experience with Lodine SR, another commercially available Wyeth product. In the background of invention section of the '171, '120, and '958 patents, the inventors disclosed that in developing extended release venlafaxine they started with the hydrogel formulation of Lodine SR. As the patent explains, however, numerous attempts to produce extended release venlafaxine tablets using hydrogel technology proved to be fruitless because "the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly."

234. The only inference that can be drawn from the inventors' choice to disclose their consideration of the failed Lodine SR formulation but not their consideration of the successful Inderal LA formulation is that they intended to deceive the patent examiner by making him believe that the Effexor XR formulation was new and novel.

c) Wyeth's Upton Patent Disclosed Extended Release Venlafaxine

235. Wyeth's own Upton patent disclosed extended release venlafaxine (*see infra*, ¶¶ 123-127). Wyeth applied for the Upton patent on January 30, 1995, more than a year before Wyeth claimed extended release venlafaxine was surprising in the '006 application. The Upton patent issued to Wyeth on April 9, 1996, one month after Wyeth filed the '006 provisional application and years before the earliest of the three patents ('171) issued (August 2001 – July 2002). This disclosure makes an extended release formulation of venlafaxine not at all surprising, especially not to Wyeth.

236. The Upton patent qualifies as prior art under 35 U.S.C. §102(e) and (f).

d) Alza's '589 PCT Application Disclosed Extended Release Venlafaxine

237. The collaboration agreement required Alza and Wyeth to exchange information about their respective efforts to develop extended release venlafaxine. The parties' Scientific Steering Committee, comprised of Alza and Wyeth employees, held one or more meetings that discussed the progress of the collaboration and other confidential information about the project, including the status of patent application filings and patent prosecution.

238. On May 27, 1993, Alza filed patent application U.S. Serial No. 08/068,480, listing inventors Edgren, *et al.* (the "Edgren application"). The Edgren application disclosed venlafaxine hydrochloride. The status of the prosecution of the Edgren application was discussed at multiple Scientific Steering Committee meetings between Wyeth and Alza, pursuant to the collaboration agreement. The Edgren application eventually matured into U.S. Patent No. 6, 440,457 on August 27, 2002 (the Edgren Patent).

239. On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the '589 PCT application). The '589 PCT application claims priority to the Edgren application. The '589 PCT application discloses once-a-day venlafaxine extended release formulations, methods for the administration of venlafaxine extended release formulations, and the hours required for *in vitro* dissolution. Once again, there was nothing surprising about the ability to extend the release of venlafaxine.

240. Both the Edgren patent and the '589 PCT application qualify as prior art to the '171, '120, and '958 patents. The earliest date of invention for Wyeth's extended release formulations is March 25, 1996, the filing date of the '006 provisional application.

241. The '589 PCT application was published on December 8, 1994, over a year before Wyeth filed the '006 application. The '589 PCT application qualifies as prior art against the

'171, '120, and '958 patents as a printed publication published in a foreign country before Wyeth invented venlafaxine hydrochloride extended release. 35 U.S.C. § 102(a). The '589 PCT application further qualifies as prior art against the '171, '120, and '958 patents as printed publications published more than one year before Wyeth filed the '006 provisional application. 35 U.S.C. § 102(b).

242. The Edgren application was filed with the PTO on May 27, 1993, roughly three years before Wyeth claimed it invented extended release venlafaxine hydrochloride (as claimed in the '006 provisional application). The Edgren inventors disclosed an extended release venlafaxine hydrochloride formulation that maintained a constant level of venlafaxine in a patient's plasma over a twenty-four hour period, which can reduce toxic effects. Because its business partner had already extended the release of venlafaxine (and claimed it in a patent), the Wyeth inventors could show nothing surprising about Wyeth's formulation efforts.

243. Because the Edgren patent qualifies as patent defeating prior art against Wyeth's '171, '120, and '958 patents as a patent application by another filed in the U.S. before Wyeth invented its controlled release formulation for venlafaxine hydrochloride. 35 U.S.C. § 102(e).

e) Wyeth Intentionally Deceived the PTO by Fraudulently Claiming it was the First to Discover, "Unexpectedly," Extended Release Venlafaxine

244. The Wyeth applicants withheld highly material information from the PTO with the intent to deceive the PTO. The Wyeth applicants had a duty to present all information that was known to be material to the patentability of the claims to the examiner. Information that is non-public, but known to the applicant, can be material to patentability. The Wyeth applicants breached their duty of candor to the PTO by failing to properly disclose Wyeth's collaboration agreement with Alza, the '589 PCT application, and the Edgren application.

245. Wyeth knew about the Edgren application and the '589 PCT application –

prior to applying for and prosecuting the '171, '120, and '958 patents – from its participation in the Scientific Steering Committee with Alza under the terms of their collaboration agreement.

246. The Wyeth applicants were aware that the '589 PCT application disclosed "controlled release dosage forms" of venlafaxine hydrochloride. The Wyeth applicants were similarly aware the '589 PCT application claimed priority back to May 27, 1993, well before Wyeth claimed to have invented its extended release venlafaxine.

247. Wyeth did disclose the existence of the '589 PCT Application to the PTO on an Informational Disclosure Statement (IDS) sent to the PTO on August 13, 1998 during the prosecution of the '328 application. Even then, it merely listed the '589 PCT Application on an information disclosure statement, with other patents. Wyeth never told the PTO that another entity claimed to have invented extended release forms of venlafaxine three years before Wyeth claimed to have invented extended release venlafaxine. Wyeth did not disclose the '589 PCT Application during the prosecution of the earlier '137 application. The Wyeth applicants each continued to misrepresent to the PTO that "[i]t was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained."

248. The collaboration agreement and the resulting '589 PCT application were material to patentability because they presented a *prima facie* case of invalidity as a prior invention of another. Wyeth inventors Sherman, Clark, Lamar and White were not the first to invent methods of (i) eliminating peaks and troughs of venlafaxine in a patient's blood plasma and (ii) reducing nausea and vomiting, via once daily dosing of venlafaxine: *Alza and its scientists, with the knowledge and collaboration of Wyeth, had developed technology and filed and prosecuted a patent application directed to those methods at least three years before Wyeth claimed its*

"unexpected" discovery. The Wyeth inventors derived at least part of their invention from the collaboration with Alza.

249. The '589 PCT application is separately material because, contrary to Wyeth's claims to discovery, it was not unexpected that one could make a controlled release venlafaxine product that eliminated the peaks and troughs of the drug in blood plasma or reduce the incidence of nausea and vomiting.

250. That the Wyeth applicants intended to deceive the PTO must be inferred from (1) their knowledge that Alza was developing an extended release version of venlafaxine, (2) Alza disclosed to Wyeth that it had filed the Edgren application and reported to Wyeth on the status of the Edgren application, (3) Wyeth was aware of the '589 PCT application (as evidenced by its late submission of the '589 PCT application to the PTO), and (4) Wyeth knew the '589 PCT application disclosed formulations of extended release venlafaxine that minimized the troughs and peaks of the amount of venlafaxine in patients' blood serum levels.

251. The Wyeth applicants' intent to deceive must also be inferred from Wyeth's financial motivation. Wyeth was aware of the impact that an Alza patent would have on Wyeth's exclusivity to sell Effexor XR. Wyeth knew that the collaborative agreement provided that Alza would own the rights to any patent that resulted from their collaboration. Alza was free to sell, use, or license the rights to the technology to a third party. Even a patent that named both Wyeth and Alza inventors would be at least co-owned, if not completely owned, by Alza. Wyeth knew that it needed its own patent to have a monopoly over extended release venlafaxine.

252. Wyeth's conspicuous withholding of the full scope of the Alza formulations, while repeatedly arguing through six patent applications that the Wyeth discovery was unexpected, shows a high level of intent to deceive the PTO.

253. Wyeth's unexpected discovery fraud directly affects claims 20-25 of the '171 patent and all of the claims of the '958 and '120 patents. And in the stark light of later patent infringement litigation, all three patents would be rendered entirely invalid and unenforceable as a result of false statements concerning "surprising" findings in developing the spheroid formulation of extended release venlafaxine, or in purportedly discovering that extending the release of venlafaxine eliminates peaks in blood plasma concentration. Because Wyeth defrauded the PTO by affirmatively but falsely claiming it had achieved "unexpected" results, Wyeth is not entitled to immunity for any claimed petitioning activity in seeking or enforcing the '171, '958, and '120 patents.

C. Wyeth Engaged in Sham Litigation against Fifteen Generic Manufacturers

254. Wyeth wrongfully listed all three of the fraudulently-obtained patents in the Orange Book. The listing of these patents was unlawful because (i) the patents were obtained through fraud, (ii) the patents were obtained deceptively, (iii) Wyeth knew that listing the patents would trigger statutory and regulatory consequences to which it was not entitled, and (iv) Wyeth knew that any litigation that might be brought on the basis of these Orange Book listings would be objectively baseless.

255. One component of Wyeth's monopolization strategy was to enforce its fraudulently-obtained patents through infringement litigation against generic manufacturers. Wyeth knew that it could not rely on the fraudulently-obtained patents to delay generic entry unless it listed them in the Orange Book because of the high legal barriers it would have to surmount in order to receive a court-ordered injunction. Thus, by taking advantage of the FDA's ministerial role in listing patents in the Orange Book, Wyeth wrongfully listed all three of the fraudulently-obtained patents in the Orange Book.

256. Wyeth's listing of the fraudulently-obtained patents compelled generic manufacturers to file Paragraph IV certifications to these patents. Thus, by using these patents to manipulate the ANDA process, Wyeth was able to delay approval of the generics' ANDAs by filing patent infringement litigation, even though the alleged infringement claims were meritless.

257. At least fifteen generic manufacturers sent Wyeth Paragraph IV certifications informing Wyeth they intended to manufacture AB-rated generic equivalents to Effexor XR and claiming their product would not infringe Wyeth's patents. In each and every instance, Wyeth reflexively sued the generic for infringement of the '171, '958, and '120 patents. Wyeth even sued branded manufacturer Osmotica, whose product was in a different form altogether (tablet instead of capsule) and was not an AB-rated generic equivalent of Effexor XR.

258. These lawsuits were pursued without either a reasonable basis or reasonable expectation of success, and were initiated solely to illegally extend Wyeth's monopoly by delaying the entrance of generic manufacturers into the relevant market.

259. Wyeth knew that all the method-of-use claims were invalid and/or unenforceable. It knew that the clinical evidence did not support its comparative statements between Effexor XR and instant release Effexor. It knew its peaks and troughs claims, broadly construed beyond the specific spheroid formulation, were simple pharmacologic tautologies. It knew that prior art existed for the formulation and method-of-use claims made in the patents. Wyeth also knew that in the context of patent infringement litigation, where sophisticated parties who will not unwittingly rely on Wyeth's deceptive statements and nondisclosures can acquire the true information about the circumstances of the acquisition of a patent, it had no reasonable likelihood of succeeding on the merits of its sixteen infringement litigations – that is, if a federal court were ever given an opportunity to reach the merits.

260. Wyeth also knew that its broad claim constructions failed to meet either the written description or the enablement requirements. In prosecuting the method claims before the PTO, Wyeth argued that they were entitled to a broad patent for the extended release formulation. The patents' specification, however, lacked any evidence that, as of the March 1996 filing date, the named inventors possessed any extended release venlafaxine formulations other than the encapsulated coated spheroid formulation described. Wyeth could not demonstrate that the inventors possessed any other possible extended release formulations covered by the patents' broad claims, thereby rendering the patents invalid for failure to satisfy the written description requirement.

261. Moreover, Wyeth knew that its overly broad claim construction rendered the patents invalid for failure to satisfy the separate enablement requirement. The broad asserted method claims, which encompass any extended release formulation of venlafaxine, were not enabled because a person of ordinary skill in the art would have to do undue experimentation in order to use the invention. The patents' specification provided no guidance or working examples for formulations other than one coated spheroid formulation.

262. The goal, purpose and/or effect of Wyeth's fraudulent procurement, wrongful listing, and sham patent suits was to prevent, delay, and/or minimize the success of the entry of generic competitors, which would have sold generic equivalents of Effexor XR in the United States at prices significantly below Wyeth's prices for Effexor XR, and therefore would have taken most of Wyeth's market share. Such generic competition would have effectively caused the average market price of Effexor XR to decline dramatically.

263. In short, for each of the seventeen lawsuits referenced below, no reasonable pharmaceutical manufacturer would believe there to be a realistic likelihood of success on the

merits. In fact, because Wyeth knew that the patents were invalid and unenforceable and that each of these cases would (if permitted to go the distance) result in a Wyeth loss, Wyeth has, so far, settled sixteen of the seventeen infringement lawsuits before a court issued a final decision on the merits.

1. Teva

264. On December 10, 2002, Teva filed an ANDA seeking approval of a generic version of Effexor XR. Teva USA's ANDA included Paragraph IV certifications that Wyeth's '171, '120, and '958 patents were invalid, unenforceable, and would not be infringed by its generic extended release venlafaxine capsules.

265. As the first ANDA applicant to submit a substantially complete ANDA, Teva USA was entitled to be the only non-authorized generic on the market for 6 months. Typically, once a drug goes generic, the branded manufacturer sells both the branded version and an "authorized" generic version, usually selling the same exact pills in different bottles. During the first filer's exclusivity period, the branded manufacturer is the *only* firm (besides the first filer) able to market and sell a competing generic version of the drug because it is permitted to do so under the authority of its approved NDA rather than under an ANDA. Launching an authorized generic permits the branded company to capture some of the revenues and profits being earned on the sales of generics.

266. On March 24, 2003, Wyeth brought suit against Teva in the District of New Jersey for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Teva with infringement of claims 20-25 of the '171 patent, claims 1, 2, 13, and 14 of the '120, and claims 1-6 of the '958 patent. All are method-of-use claims for either reducing the incidence of nausea and vomiting or smoothing out the troughs and peaks in the blood serum. Wyeth did

not assert Teva infringed any of the formulation claims. Wyeth did not claim Teva infringed any other patents.

267. Teva answered, denying the allegations and claiming that all the patents were invalid and not infringed.

268. During the *Teva* litigation, the parties disputed the term "extended release formulation" – the critical term that defines the method-of-use claims broadly, or limited to the spheroid formulation developed by Wyeth. The *Teva* court concluded that when the term "extended release formulation" is "looked at in its proper context in the specification . . . one of ordinary skill in the art would construe the term to include [the] specific ingredients" mentioned in the specification.

269. Wyeth knew this ruling meant that loss of the litigation was right around the corner. And Wyeth knew that if this ruling were permitted to stand, other generic companies could use this ruling as an already-decided issue. Wyeth could have let the Hatch-Waxman process unfold, leading to the (correct) result that a federal court would have determined the truth of Wyeth's patent coverage. It did not.

270. Instead, in late 2005 Wyeth and Teva conspired to violate the antitrust laws through a set of agreements which impaired and delayed generic competition in the market for extended release venlafaxine (the "Wyeth-Teva agreement"). Entering into an agreement of this type was a part of Wyeth's long term, overarching scheme to delay venlafaxine generics.

271. On January 20, 2006, the case was closed after the parties filed under seal a Joint Settlement and Release Agreement on November 2, 2005. All of the entities named as defendants in this complaint were signatories to that settlement agreement.

272. As part of the agreement, Teva and Wyeth agreed that the prior *Markman* ruling of the *Teva* court would be vacated. Through the vacatur, later generic companies would need to relitigate the construction of "extended release formulation" as appearing in the Wyeth patents; this would, of course, equip both Wyeth and Teva with the ability to stall later generics. The *Teva* court did, in fact, vacate its *Markman* opinion on September 6, 2005.

273. Also as part of the Wyeth-Teva agreement and as to instant release Effexor, (i) Wyeth permitted Teva to sell a generic version of (instant release) Effexor before the original compound patent for venlafaxine expired, and (ii) Wyeth agreed it would not compete with Teva's marketing of instant-release Effexor through the launch of its own authorized generic during that period.

274. The Husbands patent expired in June 2008; with Wyeth's permission, Teva obtained FDA approval and began selling generic instant release venlafaxine in October 2006 – over a year and a half before it otherwise could have.

275. Wyeth also agreed to refrain from selling an authorized generic version of (instant release) Effexor until the Husbands patent expired – giving Teva at least a year and a half of being the *only* instant release generic on the market.

276. Under the Wyeth-Teva agreement, Teva agreed to delay market entry for its ANDA-approved, AB-rated extended release venlafaxine generic until as late as July of 2010 (at which time Wyeth would not assert the patents against Teva). The agreement to delay included a provision for an earlier launch by Teva if another generic entered earlier than July of 2010, or if another generic was successful in invalidating the '171, '120 and '958 patents. To induce Teva to agree to the delay period, Wyeth promised Teva that Wyeth would not market an authorized generic version of extended release venlafaxine during at least Teva's six month "exclusivity"

and possibly longer. This launch date was more than two years after the expiration of the Husbands patent. Except in certain limited circumstances (that did not come to pass), the period of exclusivity granted Teva by Wyeth expired after Teva's 180 day FDA "exclusivity" expired and up to eleven months after Teva's launch (*i.e.*, June 1, 2011). Thus, the Wyeth-Teva agreement contemplated that Teva would have more than six months and up to *eleven* months as the sole generic seller on the market. Under the Hatch Waxman Act, Teva would have been entitled to only six months of "exclusivity" and even during those six months, Teva would not be entitled to be the *sole* generic seller, since Wyeth could have launched (and but for its anticompetitive deal, would have launched) its own authorized generic at or about the time that Teva launched its generic.

277. By entering into the Wyeth-Teva agreement, Teva agreed to delay the launch of generic Effexor XR until two years after the expiration of the only Wyeth patent actually capable of blocking generic competition to Effexor XR. As detailed further below, Teva was paid handsomely by Wyeth for its agreement not to compete with Wyeth for two years – speficially, Teva received Wyeth's agreement not to compete with Teva during Teva's period of generic "exclusivity, which agreement was worth hundreds of millions of dollars in cash profits to Teva. Teva began selling generic extended release venlafaxine capsules on or about July 1, 2010 and, pursuant to Wyeth's agreement not to compete with Teva for sales of generic extended release venlafaxine, was the only seller of generic Effexor XR until at least June 2011.

278. Taking advantage of the economic realities of the pharmaceutical industry, the Wyeth-Teva agreement worked a huge, and devastating, impact on competition in the market for extended release venlafaxine.

279. First, the agreement by Teva to delay launch of extended release venlafaxine for two years (from June of 2008 to July of 2010) meant that U.S. drug purchasers paid *billions of dollars* more for extended release venlafaxine than they otherwise would have absent the Wyeth-Teva agreement. Without the agreement, Teva would have launched the generic product no later than June of 2008.

280. Second, the agreement by Wyeth not to launch an authorized generic extended release venlafaxine during Teva's elongated "exclusivity" period meant that U.S. drug purchasers paid substantially more for extended release venlafaxine during this "exclusivity" period than they otherwise would have absent the Wyeth-Teva agreement. Without the agreement, Wyeth would have launched an authorized generic product at or about the date that Teva would have launched its generic absent the agreement (June 2008). (In fact, Wyeth eventually did launch of an authorized generic, demonstrating that it had the ability and would have launched the authorized generic earlier had it not been for the Wyeth-Teva agreement).

281. Third, Wyeth's no-authorized-generic promise constituted a substantial, net payment by Wyeth to Teva in exchange for Teva agreeing to delay generic entry much later than it otherwise would have. Under the Wyeth-Teva agreement, Wyeth did not launch its authorized generic at or about the time that Teva launched its generic in June 2010. By performing its contractual obligation not to compete with Teva, Wyeth provided Teva with a substantial financial inducement amounting to over $500 million in value in exchange for Teva's agreement to delay selling its generic version of Effexor XR for two years. Wyeth's fulfillment of its contractual obligation not to compete with Teva constituted a payment to Teva. Similarly, Wyeth's non-compete agreement *cost* Wyeth significant dollars – it lost the revenue it would have realized from the sale of inexpensively produced, competitively priced authorized generic

product, i.e., an amount likely in the range of several hundred million dollars. (Of course, Wyeth *benefited* by many billions of dollars through Teva's delayed generic entry). But while the cost to Wyeth of the promise was in the several hundreds of millions of dollars, Wyeth's no-authorized-generic promise provided a financial inducement to Teva worth about one-half billion dollars to Teva in the form of competition-free generic sales for a period of about eleven months.

282. Wyeth's no-authorized-generic promise had the purpose and effect of transferring enormous value to Teva, by ensuring that Teva would (a) garner all of the sales of generic Effexor XR during Teva's generic exclusivity period, instead of dividing those sales with Wyeth's authorized generic; and (b) charge higher prices than it would have been able to charge if it was competing with Wyeth's authorized generic. As a result, Wyeth's promise not to compete was every bit as valuable and concrete to Teva as a promise to pay Teva cash. It also had the same anticompetitive effects as a cash payment would have had – i.e., it delayed the launch of Teva's generic (and Wyeth's authorized generic) by two years, and the launch of Wyeth's authorized generic by up to an additional 11 months, depriving purchasers of the benefits of lower prices during those non-competitive periods. Wyeth, as both designed and executed, effectively caused many hundreds of millions of dollars in cash to pass from U.S. drug purchasers to Teva (some of which Teva even shared with Wyeth). This huge financial inducement served as *the* reason for Teva's delay of generic entry

283. The payment by Wyeth to Teva is all the more troubling as it represents a payment that exceeds the value that Teva could have achieved *even if it had won* the infringement litigation. If Teva had acted in a competitive manner and proceeded with the litigation to a successful conclusion, Teva would have been entitled to its "exclusivity", but it would have been required to share that "exclusivity" with Wyeth's authorized generic (which

would have entered on or before Teva's entry date absent the agreement). In these circumstances, a litigation victory would mean only six months of "exclusivity" sales, and these sales would be at quantities and prices substantially reduced by the presence of two generics, Teva's and Wyeth's authorized generic.

284. How did Teva fare better under the Wyeth-Teva agreement than if it had won the litigation? By delaying ANDA-approved and authorized generics, the Wyeth-Teva agreement caused billions in excess payments by U.S. drug purchasers that would not have occurred in a competitive environment, and Wyeth and Teva functionally split those excess profits through the provisions in the Wyeth-Teva agreement. The Wyeth-Teva agreement is not an arms-length settlement of the infringement litigation – it is an agreement between two competitors not to compete and to divide the resulting billions in excess revenues, and the resolution of the lawsuit becomes a mere conduit for a violation of the Sherman Act.

285. The payments by Wyeth to Teva cannot be excused as a litigation cost avoidance effort by Wyeth. Wyeth's projected litigation costs for the Teva litigation could not have been larger than a range of about $5 million to $10 million dollars as of the date of the Wyeth-Teva agreement, and in all events would have been the tiniest of a fraction the size of the payment likely over $500 million effectuated by Wyeth to Teva.

286. Nor can the payment be justified on any procompetitive basis. Teva provided no services or goods of any value in exchange for the payments, and no other excuse (other than generic delay) exists for the payments.

287. Furthermore, as a matter of both law and economics, the aspects of the agreement relating to the small and declining *instant* release venlafaxine market do not change the fact that the Wyeth-Teva agreement is actionable in the separate, large and growing market of *extended*

release products. In any event, any procompetitive aspects of the provisions relating to the instant release product (if any exist, which is not at all clear and in any event relatively small given the absence of instant release competitors) cannot, as a matter of law, be used to justify the anticompetitive effects of the Wyeth-Teva agreement on a different market – i.e., the extended release venlafaxine market. Moreover, any such supposed procompetitive benefits would have to be proven by Defendants and regardless, are dwarfed by the magnitude of the anticompetitive effects of the Wyeth-Teva agreement as it applies to extended release venlafaxine.

288. To add insult to injury, Teva knew that its actions in delaying the introduction of an authorized generic were brazenly anticompetitive.

289. Back in 2004, Teva had filed a citizen petition with the FDA in seeking to block Pfizer from launching an authorized generic version of its branded drug Accupril. Teva complained to the FDA that the authorized generic would "seize a significant share of the generic supply chain," that is, take generic sales from Teva. Pfizer (which acquired Wyeth in 2009) responded by explaining that stopping it from launching an authorized generic would be anticompetitive: "Teva's petition is a flagrant effort to stifle price competition – to Teva's benefit and the public's detriment" and would be "directly contrary to one of the central goals of Hatch Waxman – to promote price competition in prescription drugs[.]" Another major brand company, Johnson & Johnson, similarly told the FDA that blocking authorized generics "would be anticompetitive." The FDA denied Teva's petition, noting that an authorized generic is priced below its counterpart brand drug, that blocking an authorized generic "would unduly favor first ANDA applicants, to the detriment of the public interest that is promoted through encouragement of competition and, thereby, of lower prices in the pharmaceutical market," and concluding that "marketing [of an authorized generic] appears to promote competition in the

pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch Waxman amendments."

290. Having defeated the effort of generic companies such as Teva to stop them from launching authorized generics, brand companies unfortunately began paying generic companies to delay *their* launch of generics in exchange for the brand company promising *not* to launch an authorized generic. Such an agreement between horizontal competitors injures consumers twice over, first by prolonging the period during which only the high priced brand is available, then ensuring that generic prices are artificially inflated when generic competition finally begins by keeping the authorized generic off the market.

291. The FTC concluded in a 2011 study that: "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry. There agreements can be part of 'pay-for-delay' patent settlements, which have long concerned the Commission." See FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact at vi (2011) ("FTC Study"), available at http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf. The FTC found that an authorized generic can cut a first-filer's generic revenue by more than half during the 180-day exclusivity period, and forces generic prices down. Id. at iii, vi, 41-48, 57-59. A 2006 study sponsored by the brand drug company trade association, PhRMA, similarly, had found that an authorized generic results in lower generic prices.

292. By agreeing not to launch an authorized generic, therefore, Wyeth effectively paid Teva over $500 million dollars in exchange for Teva's promise to delay launching its generic. Effexor XR was a multi-billion drug ($2.39 billion in reported sales in 2009) before generic

competition.[12] Wyeth's payment was intended to, and did, purchase a delay in generic competition, and therefore the Wyeth-Teva agreement is unlawful and anticompetitive. Wyeth's promise not to launch an authorized generic version of Effexor XR meant that Wyeth agreed not compete on price with Teva's generic product—*i.e.*, it agreed to sell Effexor XR only at the higher branded price and not at the lower authorized generic price. This allowed Teva to maintain a supra-competitive generic price as the only generic manufacturer on the market, and to earn substantially higher profits than it otherwise would have earned, all at the expense of Plaintiffs and other generic purchasers. It also ensured that every Effexor XR prescription filled with a generic during that time period was filled with Teva's product.

293. The agreement between Wyeth and Teva was structured to encourage Wyeth to resolve all subsequent challenges to the '171, '120, and '958 patents prior to a court finding of invalidity, non-infringement, or unenforceability. The vacatur of the *Teva* court's *Markman* ruling enabled later relitigation of the critical patent construction issue. Any final ruling on the merits would trigger the need for Teva to launch its generic product, and thus (on information and belief) Wyeth's license to Teva allowed Teva to enter the market earlier than June 2010 if any subsequent generic manufacturer succeeded in establishing invalidity, non-infringement, or unenforceability of Wyeth's three patents. Because such a result would have subjected Wyeth to generic competition from Teva earlier than July 2010, the agreement gave Wyeth the incentive to resolve subsequent generic cases without a court finding of invalidity, non-infringement, or

[12] Another generic company, Apotex Corp., told the FDA that the presence of an authorized generic version of the brand drug Paxil (a brand drug with sales of $2.31 billion before generic competition, similar to Effexor XR) cost Apotex approximately $400 million. See Comment of Apotex, FDA Docket No. 2004P-0075/CP1, at 4 (Mar. 24, 2004) at http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf. And that was just during the 180-day period when Apotex would otherwise not face other generic competition. The situation here presents a larger financial inducement to Teva for the agreement not to launch an authorized generic of Effexor.

unenforceability. In fact, Wyeth resolved all of the next fifteen infringement litigations prior to any final ruling on the merits by a court.

294. Teva launched its immediate release generic Effexor tablets in August 2006. By the end of 2007, approximately 96% of Wyeth's sales of immediate release Effexor tablets worth likely about or less than $100 million had converted to Teva generic immediate release venlafaxine tablets. The availability of generic immediate release venlafaxine tablets from Teva did not significantly impact Wyeth's sales of Effexor XR.

295. On or about July 1, 2010, Teva launched its generic Effexor XR capsules. The launch of generic Effexor XR capsules caused Wyeth's sales of branded Effexor XR capsules to significantly decrease.

296. Had Wyeth not fraudulently obtained the '171, '120, and '958 patents, and/or not listed those patents in the Orange Book, and/or not brought a sham infringement lawsuit based on these patents, and/or not colluded with Teva to delay generic competition, Teva would have come to market with generic Effexor XR capsules at least by June 2008 and Wyeth would have launched an authorized generic at the same time.

2. Impax

297. Wyeth was displeased with the New Jersey *Teva* court's *Markman* ruling. So it conspired with Teva to "undo" the ruling and devised a plan to litigate infringement actions in multiple different federal courts across the country.

298. On April 5, 2006, Wyeth brought suit against Impax Laboratories, Inc. ("Impax") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Impax with infringement of claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13, and 14 of the '120 patent.

299. Impax answered, denying the allegations and claiming that all the patents were invalid, not infringed, and unenforceable.

300. Wyeth and Impax relitigated construction of the term "extended release formulation" as used in the patents. In a different court and with a different judge than it had in *Teva*, on December 13, 2007 the *Impax* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not then continue to prosecute (to an eventual ruling on the merits) whether its patent claims, as so construed, would be valid and enforceable (because any reasonable pharmaceutical manufacturer, including Wyeth, knew it would lose).

301. On May 13, 2008, an order was entered at the joint request of the parties to have the court defer ruling on pending motions for summary judgment. The parties avoided a ruling on the merits.

302. The case was closed per a consent judgment on July 15, 2008, after the parties filed under seal a Joint Settlement and Release Agreement on June 9, 2008. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed upon. Impax agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent.

303. As part of the settlement, Wyeth granted Impax a license to market its generic version of Effexor XR on June 1, 2011, (because Wyeth had promised Teva it would be the only generic Effexor XR on the market until that date) subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011.

3. Anchen

304. On April 12, 2006, Wyeth brought suit against Anchen Pharmaceuticals, Inc. ("Anchen") in the Central District of California for infringement of the '171 patent, the '120 patent, and the '958 patent. Wyeth charged Anchen with infringement of undefined claims.

305. Anchen answered, denying the allegations and claiming that all thee patents were invalid, not infringed, and unenforceable.

306. Wyeth and Anchen relitigated construction of the term "extended release formulation" as used in the patents. On December 20, 2007 the *Anchen* court issued an unpublished, in-chambers decision. Wyeth did not prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

307. The case was closed per an order on November 3, 2008 after the parties filed under seal a Joint Settlement and Release Agreement on September 26, 2008. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed. Anchen agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent; however, the agreement provides a license to Anchen on undisclosed terms.

308. The FDA approved Anchen's generic extended release venlafaxine product in or around March 16, 2012.

4. Lupin

309. On March 12, 2007, Wyeth brought suit against Lupin Ltd. ("Lupin") in the District of Maryland for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Lupin with infringement of claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1 and 2 of the '120 patent.

310. Lupin answered, denying the allegations and claiming that all three patents were invalid and not infringed.

311. Wyeth and Lupin relitigated construction of the term "extended release formulation" as used in the patents. On September 29, 2008 the *Lupin* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not then prosecute (to an eventual ruling on

the merits) whether its patent claims, as so construed, would be valid and enforceable (they would not).

312. The case was closed per an order on April 23, 2009, after the parties filed a Joint Settlement and Release Motion under seal on March 6, 2009. Under the order, the parties purported to stipulate that the patents were both valid and infringed. Lupin agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent; however, the agreement provides a license to Lupin on undisclosed terms.

5. Osmotica

313. On April 20, 2007, Wyeth brought suit against Osmotica Pharmaceuticals Corporation ("Osmotica") in the Eastern District of North Carolina for infringement of the '171 patent, the '120 patent, and the '958 patent. Wyeth charged Osmotica with infringement of the "asserted claims" which include claims 1-6 of the '958 patent and claim 1 of the '120 patent. The parties disputed the term "extended release formulations."

314. Osmotica sought to market a *tablet* form of extended release venlafaxine, not an generic version of Wyeth's Effexor XR. Osmotica's NDA sought approval under the hybrid provisions of 505(b)(2) of the FDCA. Osmotica's product, by definition, was not an AB-rated generic equivalent of Effexor XR.

315. Osmotica answered, denying the allegations and claiming that all three patents were invalid, non-infringed, and unenforceable.

316. The case was closed per an order on March 19, 2008 after the parties filed under seal a Joint Settlement and Release Agreement on March 17, 2008. Under the order, Osmotica agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent; however, the agreement provides a license to Osmotica on undisclosed terms.

6. Sandoz

317. On June 22, 2007, Wyeth brought suit against Sandoz, Inc. ("Sandoz") in the Eastern District of North Carolina for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Sandoz with direct infringement, active inducement of infringement, and contributory infringement of claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13, and 14 of the '120 patent.

318. Sandoz answered, denying the allegations and claiming that all three patents were invalid, not infringed, and unenforceable.

319. Wyeth and Sandoz relitigated construction of the term "extended release formulation" as used in the patents. On July 3, 2008, the *Sandoz* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

320. The case was closed per an order on August 8, 2011 after the parties filed a stipulation of dismissal and a consent order. Under the order, Sandoz agreed not to enter the market until expiration of the '171 patent, the '120 patent, and the '958 patent except to the extent permitted under agreements between Wyeth and Sandoz (that were not reflected as having been filed with the court).

7. Mylan

321. On July 6, 2007, Wyeth brought suit against Mylan Pharmaceuticals Inc. ("Mylan") in the Northern District of West Virginia for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Mylan with direct infringement, active inducement of infringement, and contributory infringement of claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13, and 14 of the '120 patent.

322. Mylan answered, denying the allegations and claiming that all three patents were invalid and not infringed.

323. Wyeth and Mylan relitigated construction of the term "extended release formulation" as used in the patents. On May 22, 2009 the *Mylan* court issued a decision in Wyeth's favor on that issue.

324. The *Mylan* case proceeded to some summary judgment determinations, none of which would resolve the case. As part of its summary judgment briefing, Wyeth found itself in a conundrum; Wyeth argued that its broad method-of-use claims were enabled because anyone in the art could make the broad range of "extended release formulations" of venlafaxine, but that this enablement did not contradict its representations to the PTO that its formulation of slowing the release of venlafaxine was "completely unexpected . . .".

325. On October 14, 2009 an order denied, in part, and granted, in part, Mylan's motions for summary judgment. Judge Keeley denied Mylan's motions regarding infringement and enablement, and granted Wyeth's motion regarding inventorship. Wyeth did not seek summary judgment on other bases. Mylan's other defenses, including its invalidity defenses, remained unresolved.

326. Wyeth did not then prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

327. The case was closed per a dismissal order on December 21, 2009 after the parties filed under seal a Joint Settlement and Release Motion on November 30, 2009. Under the order, Mylan agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Mylan on undisclosed terms. Mylan launched a generic in or about June 2011.

8. Biovail

328. On June 26, 2008, Wyeth brought suit against Biovail Corporation ("Biovail") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Biovail with infringement of undefined claims.

329. Biovail answered, denying the allegations and claiming that all three patents were invalid and not infringed.

330. The *Biovail* case only lasted nine months. The case was closed per an order on March 19, 2010 after the parties filed under seal a Joint Motion to Enter Consent Judgment and to Enter Stipulated Order on November 12, 2009. Under the order, the parties purported to stipulate that the patents were both valid and infringed. Biovail agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Biovail on undisclosed terms.

9. Apotex

331. On August 18, 2008, Wyeth brought suit against Apotex Inc. and Apotex Corp. ("Apotex") in the Southern District of Florida for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Apotex with infringement of claims 2-20 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13, and 14 of the '120 patent.

332. Apotex answered, denying the allegations and claiming that all three patents were invalid, not infringed and unenforceable for inequitable conduct.

333. Wyeth and Apotex relitigated construction of the term "extended release formulation" as used in the patents. On August 13, 2009 the *Apotex* court issued a decision in Wyeth's favor on that issue. However, Wyeth did not prosecute to an eventual ruling on the merits whether its patent claims, as so construed, would be valid and enforceable (they would not).

334. The case was closed per an order on September 15, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on August 11, 2010. Under the order, the parties purported to stipulate that the patents were valid, enforceable, and infringed. Apotex agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Apotex on undisclosed terms. Apotex launched a generic in or about June 2011.

10. Torrent

335. On January 8, 2009, Wyeth brought suit against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. ("Torrent") in the District of Delaware for infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Torrent with infringement of claims undefined.

336. Torrent answered, denying the allegations and claiming that all three patents were invalid and not infringed.

337. The case was closed per an order on June 30, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on May 6, 2010. Under the order, the parties purported to stipulate that the patents were both valid and infringed. Torrent agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement provides a license to Torrent on undisclosed terms. The FDA approved Torrent's generic extended release venlafaxine product in or around June 1, 2011 and Torrent launched a generic at or about that time.

11. Cadila

338. On April 9, 2009, Wyeth brought suit against Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) ("Cadila") in the District of Delaware for infringement of the

‘171 patent, the ‘120 patent and the ‘958 patent. Wyeth charged Cadila with infringement of claims undefined.

339. Cadila answered, denying the allegations and claiming that all three patents were invalid and not infringed.

340. The case was closed per an order on March 30, 2010 after the parties filed under seal a Joint Settlement and Release Agreement on January 28, 2010. Under the order, the parties purported to stipulate that the patents were valid and infringed. Cadila agreed not to enter the market until expiration of the ‘171 patent, the ‘120 patent and the ‘958 patent; however, the agreement provides a license to Cadila on undisclosed terms. The FDA approved Cadila’s generic extended release venlafaxine product in or around April 14, 2011 and Cadila launched a generic in or about June 2011.

12. Aurobindo

341. On April 22, 2010, Wyeth brought suit against Aurobindo Pharma Limited (“Aurobindo”) in the District of New Jersey for the infringement of the ‘171 patent, the ‘120 patent and the ‘958 patent. Wyeth charged Aurobindo with infringement of claims undefined.

342. Aurobindo answered, denying the allegations and claiming that all three patents were invalid and not infringed.

343. The case was closed per an order on January 6, 2011. The parties purported to stipulate that the patents were valid and infringed upon. Aurobindo agreed not to enter the market until expiration of the ‘171 patent, the ‘120 patent and the ‘958 patent; however, the agreement between Wyeth and Aurobindo provides a license to Aurobindo on undisclosed terms. The FDA approved Aurobindo’s generic extended release venlafaxine product in or around April 14, 2011 and Aurobindo launched a generic in or about June 2011.

13. Orgenus and Orchid

344. On July 2, 2009, Wyeth brought suit against Orgenus Pharma Inc. and Orchid Chemicals and Pharmaceuticals (collectively, "Orchid") in the District of New Jersey for the infringement of the '171 patent, the '120 patent and the '958 patent. Wyeth charged Orchid with infringement of claims undefined.

345. Orchid answered, denying the allegations and claiming that all three patents were invalid, unenforceable, and not infringed.

346. A consent order of final judgment was entered on April 14, 2011. The parties purported to stipulate that the patents were valid and infringed. Orchid agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent; however, the agreement between Wyeth and Orchid provides a license to Orchid on undisclosed terms. The FDA approved Orchid's generic extended release venlafaxine product in or around July 11, 2011.

14. Intellipharmaceutics

347. On July 1, 2010 Wyeth brought suit against Intellipharmaceutics International Inc., Intellipharmacutics Corporation, and Intellipharmaceutics LTD (collectively, "Intellipharmaceutics") in the Southern District of New York for the infringement of the '171 patent, the '120 patent, and the '958 patent. Wyeth charged Intellipharmaceutics with infringement of claims undefined.

348. Intellipharmaceutics answered, denying the allegations and claiming that all three patents were invalid, unenforceable, and not infringed.

349. A consent order of final judgment was entered on June 20, 2011. The parties purported to stipulate that the patents were valid and infringed. Intellipharmaceutics agreed not to enter the market until expiration of the '171 patent, the '120 patent and the '958 patent;

however, the agreement between Wyeth and Intellipharmaceutics provides a license to Intellipharmaceutics on undisclosed terms.

15. Wockhardt

350. On August 8, 2007, Wyeth brought suit against Wockhardt USA LLC ("Wockhardt") in the Central District of California for infringement of the '171 patent, the '120 patent and the '958 patent.

351. Wockhardt answered, denying the allegations and claiming that all thre e patents were invalid, unenforceable, and not infringed.

352. On May 29, 2008, the district court denied Wyeth's motion to dismiss Wockhardt's inequitable conduct allegations. Trial was scheduled for September 14, 2010.

353. The case was closed per an order on May 19, 2009 after the parties filed under seal a Joint Settlement and Release Agreement.

354. As part of the settlement, Wyeth agreed that Wockhardt could enter the market with its generic version of Effexor XR on June 1, 2011, subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011.

355. The FDA approvel Wockhardt's generic extended release venlafaxine product on or around April 14, 2011. Wockhardt launched its generic Effexor XR on or about June 1, 2011.

16. Dr. Reddy's

356. On September 3, 2010, Wyeth brought suit against Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's") in the District of New Jersey for infringement of the '171 patent, the '120 patent, and the '958 patent.

357. Dr. Reddy's answered, denying the allegations and claiming that all three patents were invalid and not infringed.

358. The case was closed by an order dated April 28, 2011, after the parties settled entered into a Stipulation and Order of dismissal on April 25, 2011.

359. As part of the settlement, Wyeth agreed that Dr. Reddy's could enter the market with its generic version of Effexor XR on June 1, 2011, subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011. The FDA approved Dr. Reddy's generic extended release venlafaxine product on May 6, 2011 and Dr. Reddy's launched a generic in or about June 2011.

17. Nostrum

360. On April 21, 2011, Wyeth brought suit against Nostrum Laboratories, Inc., Nostrum Pharmaceuticals, LLC, and Enem Nostrum Remedies Pvt. Ltd. in the District of New Jersey for infringement of the '171 patent, the '120 patent, and the '958 patent.

361. On February 8, 2012 – before Nostrum had answered Wyeth's complaint – the parties filed a stipulation of dismissal. On February 10, 2012, the Court entered an order dismissing the case.

362. Nostrum agreed not to enter the market until expiration of the '171, '120 and '958 patents; the agreement provides a license to Nostrum on undisclosed terms.

D. Earlier Allegations and Evidence of the Invalidity and Unenforceability of Wyeth's '171, '120, and '958 Patents

363. In patent infringement litigation against generic manufacturers, allegations about validity or enforceability, or rulings on the merits against a patent holder, are the kind of developments that taint the patent with an issue regarding its validity or enforceability.

364. Here, Wyeth asserted sixteen different generic manufacturers infringed the method-of-use claims. Simply by filing suit, Wyeth kept each of the sixteen generic equivalents of Effexor XR off the market for the shorter of two-and-a-half years or a decision on the merits.

In answering Wyeth's claim of infringement, each of the generic companies claimed that the patents were invalid. Several of the generic companies also alleged the patents were unenforceable due to inequitable conduct. The validity and enforceability was to be actively litigated between Wyeth and the generic manufacturers.

365. However, Wyeth settled each and every Effexor XR infringement suit before a federal court could render an opinion on the validity or enforceability of Wyeth's patents. Wyeth orchestrated settlements with the generics in order to bring an end to the litigation it started before a court could find the asserted method-of-use claims invalid or unenforceable.

366. Despite Wyeth's instituting sixteen infringement lawsuits, and despite would-be generic competitors' allegations and evidence of invalidity and unenforceability, no court entered an order determining the invalidity or enforceability of the fraudulently-obtained method-of-use claims. The only court to issue a substantive decision on the merits denied Wyeth's motion for summary judgment regarding infringement but did not determine whether or not the patents themselves were valid and/or enforceable. In the rare instances where litigation with the generics approached either a summary judgment decision addressing invalidity/enforceability or a trial date, Wyeth settled with the generics.

367. Wyeth cannot insulate itself from liability for the anticompetitive effects of its fraudulent procurement of the method-of-use claims by bringing lawsuits it knew it would lose and settling with the alleged infringing generic companies before the merits can be adjudicated. If the terms are favorable, generic manufacturers have a significant incentive to accept Wyeth's offer. But prescription drug purchasers are still harmed by Wyeth's anticompetitive scheme and sham litigation.

368. Settlement by the parties to the infringement actions cannot preclude those harmed by the anticompetitive effects of Wyeth's wrongful actions (in both obtaining the patents and filing infringement suits) from seeking recovery for their damages.

369. Wyeth's conduct in procuring the illegal listing of the fraudulently-obtained '171, '120, and '958 patents in the Orange Book is not entitled to immunity under the Noerr-Pennington doctrine because: (i) the FDA's listing of the fraudulently-obtained patents was a purely ministerial act, and thus Wyeth's conduct before the FDA does not constitute legally protected petitioning activity, (ii) the Noerr-Pennington doctrine does not immunize or protect the act of deceiving the FDA, (iii) no immunity applies to Wyeth's anticompetitive acts in structuring arrangements with Teva that delayed generic entry and allocated markets, and (iv) no immunity applies to this overall scheme.

370. Likewise, the Noerr-Pennington doctrine does not immunize Wyeth's patent infringement suits from antitrust liability, because each of the patent litigation actions brought by Wyeth was an objectively baseless "sham," which no litigant could reasonably have expected to win, and was prosecuted solely for the purpose of delaying entry of generic competition into the relevant market for extended release venlafaxine.

371. Wyeth's overarching scheme to improperly use patent to manipulate the ANDA process and wrongfully delay generic competition is not immunized because Wyeth's scheme was intended to, and did, unlawfully maintain its monopoly over the relevant market for extended release venlafaxine hydrochloride capsules.

VI. MONOPOLY POWER AND MARKET DEFINITION

372. At all relevant times, Wyeth had monopoly power over Effexor XR and its generic equivalents because it had the power to maintain the price of the drug it sold as Effexor XR at supra-competitive levels without losing substantial sales to other products prescribed

and/or used for the same purposes as Effexor XR, with the exception of generic extended release venlafaxine hydrochloride capsules.

373. A small but significant, non-transitory price increase by Wyeth for Effexor XR would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Effexor XR, with the exception of generic extended release venlafaxine hydrochloride capsules.

374. Because of, among other reasons, psychotropic drugs' heterogeneous responses in different patient populations, Effexor XR is differentiated from all products other than AB-rated generic versions of Effexor XR.

375. Wyeth needed to control only Effexor XR and its AB-rated generic equivalents, and no other products, in order to maintain the price of Effexor XR profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Effexor XR would render Wyeth unable to profitably maintain its current prices of Effexor XR without losing substantial sales.

376. Wyeth also sold Effexor XR at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

377. Wyeth has had, and exercised, the power to exclude competition to Effexor XR.

378. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is all extended release venlafaxine hydrochloride capsules – *i.e.*, Effexor XR (in all its forms and dosage strengths) and AB-rated bioequivalent extended release venlafaxine hydrochloride capsules. During the period relevant to this case, Wyeth has been able to profitably maintain the price of Effexor XR well above competitive levels.

379. Wyeth, at all relevant times, enjoyed high barriers to entry with respect to competition to the above defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

380. The relevant geographic market is the United States and its territories.

381. Wyeth's market share in the relevant market was 100% until June of 2010, implying a substantial amount of monopoly power.

VII. MARKET EFFECTS

382. Wyeth, acting alone and/or in concert with Teva, willfully and unlawfully maintained its monopoly power by engaging in an overarching scheme to exclude competition that discouraged rather than encouraged competition on the merits. This scheme was designed for the anticompetitive purpose of forestalling generic competition and carried out with the anticompetitive effect of maintaining supra-competitive prices for the relevant product. Wyeth implemented its scheme by, inter alia, improperly listing patents in the Orange Book, manipulating the prosecution of the '171, '958, and '120 patents, prosecuting multiple sham patent infringement lawsuits, and abusing the Hatch-Waxman framework, in concert with Teva (through the Wyeth-Teva agreement), to serve its anticompetitive goals. These acts in combination and individually were anticompetitive.

383. Wyeth's acts and practices, including its conspiracy with Teva, had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Effexor XR (and later Teva's generic version of Effexor XR) from generic competition. Wyeth's actions, including its conspiracy with Teva, allowed it to maintain a monopoly and exclude competition in the market for extended release venlafaxine hydrochloride capsules, *i.e.*, Effexor XR and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Direct Purchaser Class.

384. Wyeth's exclusionary conduct, including its conspiracy with Teva, has delayed generic competition and unlawfully enabled it to sell Effexor XR without generic competition. But for the illegal conduct of Wyeth and/or Teva, one or more generic competitors would have begun marketing AB-rated generic versions of Effexor XR much sooner than they actually were marketed, and, in any events, would have been on the market no later than June 14, 2008. By way of examples and not limitation: (i) if there had been no fraud upon the PTO, the '171, '958, and '120 patents would not have issued, the patents would never have been listed in the Orange Book, and thus the patents would never have been the subject of infringement litigation that led to the 30 month Hatch-Waxman stay; (ii) if there had been no patents, there would have been no lawsuits, and with no lawsuits there would have been no settlements, all of which acted to further delay FDA approval and the timing of generic launch; (iii) if the lawsuits had not been brought, the 30 month Hatch-Waxman stay would never have been triggered, no settlements would have been necessary, and FDA approval would have been forthcoming by June of 2008 with generic makers ready, willing, and able to launch at that time; and (iv) if the settlement agreement had not occurred Teva would have earlier entered the market and/or the patents would easily have been invalidated, and permitted generic entry, much earlier.

385. The generic manufacturers seeking to sell generic Effexor XR had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic manufacturers would have been ready, willing and able to launch its generic version of Effexor XR by June, 2008 were it not for Wyeth's illegal acts and conspiracies with Teva.

386. Wyeth's illegal acts and conspiracy with Teva, to delay the introduction into the U.S. marketplace of any generic version of Effexor XR caused Plaintiffs and the Class to pay

more than they would have paid for extended release venlafaxine hydrochloride capsules, absent this illegal conduct.

387. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, direct purchasers' purchases of brand drugs are rapidly substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

388. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Wyeth, direct purchasers, such as Plaintiffs and members of the Class, would have paid less for extended release venlafaxine hydrochloride capsules by (a) substituting purchases of less-expensive AB-rated generic Effexor XR for their purchases of more-expensive branded Effexor XR, (b) receiving discounts on their remaining branded Effexor XR purchases, and/or (c) purchasing generic Effexor XR at lower prices sooner.

389. Likewise, the Wyeth-Teva agreement had the purpose and effect of preventing competition from Wyeth's authorized generic version of Effexor XR, thereby causing Plaintiffs

and members of the Class to purchase generic Effexor XR at supracompetitive prices during Teva's period of generic "exclusivity" (and beyond).

390. Thus, the unlawful conduct of Defendants, and each of them, deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

391. During the relevant period, Plaintiffs and members of the Direct Purchaser Class purchased substantial amounts of Effexor XR directly from Wyeth and/or purchased substantial amounts of generic Effexor XR directly from Teva. As a result of Defendants' illegal conduct, members of the Direct Purchaser Class were compelled to pay, and did pay, artificially inflated prices for their extended release venlafaxine hydrochloride capsule requirements. Those prices were substantially greater than the prices that members of the Direct Purchaser Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Effexor XR was artificially inflated by Defendants' illegal conduct; (2) Direct Purchaser Class members were deprived of the opportunity to purchase lower-priced generic versions of Effexor XR sooner; and/or (3) the price of generic Effexor XR was artificially inflated by Defendants' illegal conduct.

392. As a consequence, Plaintiffs and members of the Direct Purchaser Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

393. Wyeth's efforts to monopolize and restrain competition in the market for extended release venlafaxine hydrochloride capsules have substantially affected interstate and foreign commerce.

394. At all material times, Wyeth manufactured, promoted, distributed, and sold substantial amounts of Effexor XR in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

395. At all material times, Wyeth transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Effexor XR.

396. In furtherance of their efforts to monopolize and restrain competition in the market for extended release venlafaxine hydrochloride capsules, Wyeth employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Wyeth's activities were within the flow of and have substantially affected interstate commerce.

IX. CLASS ACTION ALLEGATIONS

397. Plaintiffs, on behalf of themselves and all Direct Purchaser Class members, seek damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for Effexor XR and AB-rated generic equivalents.

398. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of a Direct Purchaser Class defined as follows:

> All persons or entities in the United States and its territories who purchased Effexor XR and/or AB-rated generic versions of Effexor XR directly from any of the Defendants at any time during the period June 14, 2008 through and until the anticompetitive effects of the defendants' conduct cease (the "Class Period").

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

399. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class numbers in the many scores of entities. Further, the Direct Purchaser Class is readily identifiable from information and records in the possession of the Defendants.

400. Plaintiffs' claims are typical of the claims of the members of the Direct Purchaser Class. Plaintiffs and all members of the Direct Purchaser Class were damaged by the same wrongful conduct of the Defendants, *i.e.*, they paid artificially inflated prices for extended release venlafaxine hydrochloride capsules and were deprived of earlier and more robust competition from cheaper generic versions of Effexor XR as a result of Defendants' wrongful conduct.

401. Plaintiffs will fairly and adequately protect and represent the interests of the Direct Purchaser Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the Direct Purchaser Class.

402. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

403. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Direct Purchaser Class thereby making overcharge damages with respect to the Direct Purchaser Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

404. Questions of law and fact common to the Direct Purchaser Class include:

a. whether Wyeth willfully obtained and/or maintained monopoly power over Effexor XR and its generic equivalents;

b. whether Wyeth improperly listed the '171, '120, and '958 patents in the Orange Book;

c. whether Wyeth unlawfully excluded competitors and potential competitors from the market for Effexor XR and its AB-rated generic bioequivalents;

d. whether Wyeth unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

e. whether Wyeth maintained monopoly power, itself and/or in conspiracy with Teva, by delaying generic entry;

f. whether Wyeth and Teva entered into an illegal contract, combination, conspiracy and/or other agreement in restraint of trade;

g. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

h. whether Defendants' activities as alleged herein have substantially affected interstate commerce;

i. whether, and if so to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

j. the quantum of aggregate overcharge damages to the Class.

405. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

406. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. CLAIMS FOR RELIEF

COUNT ONE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)

(Asserted Against Wyeth)

407. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

408. As described above, from October 1997 until at least June 2010 (and with effects lasting far longer), Wyeth possessed monopoly power in the market for extended release venlafaxine hydrochloride capsules. No other manufacturer sold a competing version of extended release venlafaxine, whether branded or generic, before June 2010.

409. Wyeth willfully and unlawfully maintained its monopoly power in the extended release venlafaxine hydrochloride capsule market from June 2008 through at least June 2010 by engaging in an anticompetitive scheme to keep generic equivalents from the market – not as a result of providing a superior product, business acumen, or historical accident.

410. Wyeth knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rated generic versions of Effexor XR to maintain its monopoly power. This scheme included:

a. obtaining the ‘171, ‘958, and ‘120 patents by misleading the PTO and failing to exercise the duty of good faith;

b. improperly listing the ‘171, ‘958, and ‘120 patents in the Orange Book;

c. engaging in sham litigation;

d. prolonging the impact of their serial sham litigation through settlement arrangements that further delayed generic entry; and

e. negotiating settlements with subsequent generic applicants to preserve and protect its monopoly and the market-division agreement negotiated with Teva.

411. By means of this scheme, Wyeth intentionally and wrongfully maintained monopoly power with respect to Effexor XR in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their extended release venlafaxine hydrochloride capsule requirements.

412. Plaintiffs and members of the Class have been injured in their business or property by Wyeth's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their extended release venlafaxine hydrochloride capsule requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Wyeth's conduct unlawful, and Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

413. Wyeth's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

414. Wyeth knowingly and intentionally engaged in sham litigation against manufacturers of AB-rated generic equivalents of Effexor XR. Wyeth repeatedly asserted that generic manufacturers extended release venlafaxine formulations infringed its '171, '120, and '958 patents, thereby automatically keeping each generic competitor off the market for at least 30 months. Wyeth intentionally and deceptively alleged the generic manufacturers' products infringed its patents. For each infringement suit, Wyeth knew at the time it filed that it had no realistic likelihood of success; that is, no realistic likelihood that a court would enforce the fraudulently-obtained '171, '958 and '120 patents against a generic company. Wyeth knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a

reasonable chance of succeeding on the merits of these infringement lawsuits. Wyeth filed these sham lawsuits for the purposes of using a governmental process (including the automatic 30 month stay of FDA approval) as an anticompetitive weapon to keep generics off the market.

415. Wyeth engaged in serial sham lawsuits as part of a pattern or practice of successive filing undertaken for the purposes of harassment, injuring market rivals, and unreasonably delaying generic entry. Wyeth filed fourteen different lawsuits, all asserting unenforceable patents, for purposes of harassing generic manufacturers, keeping generics off the market, and preserving its Effexor XR monopoly. Wyeth settled each lawsuit before a court could find the patents unenforceable and negotiated deals with the generic companies that kept the first generic off the market until June 2010 and rest of the market until June 2011.

416. Wyeth engaged in distinct *Walker Process* frauds.

417. First, Wyeth obtained method-of-use claims for extended release venlafaxine by fraudulently claiming clinical data showed Effexor XR reduced the incidence of nausea and vomiting associated with instant release Effexor. Wyeth knew that its clinical data did not show a decreased incidence of nausea. Wyeth knew that this information would be material to the patent examiner. Wyeth intentionally withheld the truth about the clinical data in order to defraud the patent examiner into issuing patents that included method-of-use claims for the reduction in the incidence of vomiting.

418. Second, Wyeth obtained method-of-use claims for extended release venlafaxine by, first, failing to disclose its own Upton patent disclosed extended release venlafaxine and, later, failing to disclose that a patent examiner had found all method-of-use claims unpatentable in light of the Upton patent. Wyeth knew that both the Upton patent and the examiner's rejection of the method-of-use claims in light of the Upton patent would be material to the later patent

examiner. Wyeth intentionally withheld the Upton patent and the related examiner's rejection in order to defraud the patent examiner into issuing patents that included method-of-use claims.

419. Third, Wyeth fraudulently claimed that an extended release version of Effexor was unexpected, despite knowing the Upton patent and the '589 PCT application previously disclosed extended release versions of Effexor. Wyeth intentionally failed to inform the examiner about the prior disclosures of extended release venlafaxine and further failed to correct its fraudulent representation that an extended release version of venlafaxine was surprising in order to defraud the patent examiner into issuing patents that pertained to Effexor XR.

420. Fourth, Wyeth obtained patent claims for extended release venlafaxine by misrepresenting that it was "completely unexpected" that an extended release venlafaxine hydrochloride formulation could be obtained despite knowing and failing to disclose to the examiner that it developed the Effexor XR formulation by substituting venlafaxine for propranolol in the extended release formulation for its pre-existing Inderal LA product. Contrary to the representation to the PTO, Wyeth expected this formulation to work because venlafaxine and propranolol have similar solubilities in water and peak blood levels that occur in about six hours.

COUNT TWO
CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 1)

(Asserted against all Defendants)

421. Plaintiffs repeat and incorporate by reference all preceding paragraphs and allegations.

422. Beginning in or about 2005, Wyeth and Teva engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which were

to (i) prevent the sale of generic versions of extended release venlafaxine hydrochloride capsules in the United States for a period of about two years, thereby protecting Effexor XR from any generic competition during that time, (ii) allocate all sales of extended release venlafaxine hydrochloride capsules in the United States, (iii) elongate the 6 month Hatch-Waxman exclusivity period for the first generic ANDA filer (Teva), (iv) delay the introduction of an authorized generic of extended release of venlafaxine hydrochloride capsules which otherwise would have appeared on the market at a significantly earlier time, and (v) effectively fix the price that the Plaintiffs and the other members of the direct purchaser class would need to pay for extended release venlafaxine hydrochloride capsules.

423. By entering into this unlawful conspiracy, Wyeth and Teva have unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Wyeth and Teva are horizontal market allocation and price fixing agreements between actual or potential competitors and are unreasonable restraints of trade in violation of Section 1 under the "rule of reason" mode of analysis.

424. Plaintiffs and all members of the Direct Purchaser Class have been injured in their business and property by reason of the unlawful contracts, combinations and/or more conspiracies. Plaintiffs and members of Direct Purchaser Class have paid more on their purchases of extended release venlafaxine hydrochloride capsules than they would otherwise had paid, and/or were prevented from substituting a less expensive, generic alternative for their purchases of the more expensive Effexor XR and/or Teva's more expensive generic Effexor XR.

425. As a result of Defendants' illegal conduct, Plaintiffs and the Class paid more than they would have paid for extended release venlafaxine hydrochloride capsules, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun

marketing generic versions of extended release venlafaxine hydrochloride (including Wyeth's authorized generic) well before June of 2010, and/or would have been able to market such versions more successfully.

426. If manufacturers of generic extended release venlafaxine hydrochloride capsules entered the market and competed with Effexor XR in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic extended release venlafaxine hydrochloride capsules for the higher-priced brand name Effexor XR for some or all of their extended release venlafaxine hydrochloride capsule requirements, and/or would have paid lower prices on some or all of their remaining Effexor XR and/or generic Effexor XR purchases.

427. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of extended release venlafaxine hydrochloride capsules directly from one or both of the Defendants. As a result of Defendants' illegal conduct, alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their extended release venlafaxine hydrochloride capsule requirements. Plaintiffs and the other Class members paid prices for extended release venlafaxine hydrochloride capsules that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to earlier purchase lower-priced generic extended release venlafaxine hydrochloride capsules instead of expensive brand name Effexor XR; (2) Class members were forced to pay artificially inflated prices for generic extended release venlafaxine hydrochloride capsules; and/or (3) the price of brand name Effexor XR was artificially inflated by Defendants' illegal conduct.

XI. DEMAND FOR JUDGMENT

428. WHEREFORE, Plaintiffs, on behalf of themselves themselves and the Direct Purchaser Class, respectfully request that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiffs the representative of the Direct Purchaser Class;

b. Enter judgment against Wyeth and Teva in favor of Plaintiffs and the Direct Purchaser Class;

c. Adjudge and decree the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

d. Award the Direct Purchaser Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

e. Award Plaintiffs and the Direct Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law; and

f. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Wyeth's unlawful conduct, as the Court deems just.

XII. JURY DEMAND

429. Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of themselves and the proposed class demand a trial by jury on all issues so triable.

Dated: October 23, 2013

Respectfully submitted,

/s/ Peter S. Pearlman
Peter S. Pearlman

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